

Risk Factors Comparison 2025-03-03 to 2024-03-07 Form: 10-K

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Investing in shares of our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all of the other information contained in this Annual Report on Form 10-K, including our audited consolidated financial statements and related notes and the section titled “ Management’ s Discussion and Analysis of Financial Condition and Results of Operations, ” before making an investment decision. The risks described below are not the only ones facing us. Many of the following risks and uncertainties are, and will be, exacerbated by any worsening of the global business and economic environment. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition, reputation, or results of operations. In such case, the trading price of shares of our common stock could decline, and you may lose all or part of your investment.

Summary Risk Factors • We are a clinical- stage biopharmaceutical company and have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability. Our substantial contingent consideration and related obligations from our acquisitions of assets and license and collaboration agreements may result in dilution to our stockholders, may be a drain on our cash resources, or may cause us to incur debt obligations to satisfy the payment obligations. Our limited operating history may make it difficult to evaluate our prospects and likelihood of success. We will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts. If we are unable to successfully identify, develop and commercialize any product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected. We were founded with a mission to redefine neuroscience drug development, a field that has seen very limited success. The ability to successfully develop drugs in this field is extremely difficult and is subject to a number of unique challenges. We have invested and expect to continue to invest in acquiring product candidates, technologies and assets, as well as research and development efforts that further enhance our product pipeline. Such investments may affect our operating results, and, if the return on these investments is lower or develops more slowly than we expect, our revenue and operating results may suffer. We have experienced rapid growth since our inception in November 2019, ~~and expect to continue to grow in the future.~~ If we fail to effectively manage our growth, we may not be able to execute on our business objectives. We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do. Clinical and preclinical drug development is a lengthy and expensive process, with an uncertain outcome. Our clinical and preclinical programs have experienced delays and may experience additional delays or may never advance, which would adversely affect our ability to obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which could have an adverse effect on our business. The development and commercialization of drug products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time- consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates on a timely basis or at all, our business will be substantially harmed. We depend on intellectual property licensed from third parties and we are currently party to in- license agreements under which we acquired rights to use, develop, manufacture and / or commercialize certain of our proprietary technologies and product candidates. If we breach our obligations under these agreements or if any of these agreements is terminated, or otherwise experience disruptions to our business relationships with our licensors, we may be required to pay damages, lose our rights to such intellectual property and technology, or both, which would harm our business.

Risks Related to Our Limited Operating History, Financial Condition and Need for Additional Capital ~~Capital~~ **We** ~~We~~ are a clinical - stage biopharmaceutical company and have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability. We are a clinical - stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have incurred significant losses since our inception in November 2019, have no products approved for commercial sale, have not generated any revenue from product sales, have financed our operations principally through proceeds from sales of common stock, convertible preferred stock and convertible promissory notes and expect to incur significant losses for the foreseeable future. We expect that it will be several years before we have a commercialized product and generate revenue from product sales, **if at all.** ~~As of~~ **Our net loss was \$ 235.9 million and \$ 130.9 million for the years ended December 31, 2023-2024 and 2022, respectively.** ~~As of December 31, 2023-~~, we had an accumulated deficit of \$ ~~703.947.~~ **42** million. Our losses have resulted principally from acquired in- process research and development from our acquisitions of assets, expenses incurred in the research and development of our product candidates, as well as from costs associated with our preclinical studies and clinical trials and management and administrative costs and other expenses that we have incurred while building our business infrastructure. We expect our expenses and operating losses will continue to increase substantially for the foreseeable future as we expand our research and development efforts, advance our clinical candidates to potentially registrational trials, identify and acquire product candidates, complete preclinical studies and initiate additional clinical trials, seek regulatory approval and commercialization of our product candidates and operate as a public company. We anticipate that our expenses will continue to increase substantially as we: • continue clinical and preclinical development of our current and future product candidates and initiate additional preclinical studies and clinical trials; • seek regulatory approval of our current

and future product candidates; • acquire additional product candidates, technologies, multimodal patient datasets and other assets for our business; • expand our operational, financial and management systems and increase personnel, including personnel to support our clinical and preclinical development, manufacturing and commercialization efforts; • continue to develop, perfect, maintain and defend our intellectual property portfolio; and • incur additional legal, accounting or other expenses in operating our business, including the additional costs associated with operating as a public company. We have devoted a significant portion of our financial resources and efforts to building our organization, acquiring technologies and companies, executing clinical and preclinical studies, conducting research and development, identifying and developing potential product candidates, building our precision neuroscience approach, organizing and staffing our company, business planning, establishing, maintaining and protecting our intellectual property portfolio, raising capital and providing general and administrative support for these operations. We have not completed development and commercialization of any of our product candidates with most still being in relatively early development. To become and remain profitable, we must succeed in identifying, developing, conducting successful clinical trials, obtaining regulatory approval for, and eventually commercializing, products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, continuing to discover and develop additional product candidates, obtaining regulatory and marketing approval for any product candidates that successfully complete clinical trials, accessing manufacturing capacity, establishing marketing capabilities, commercializing and ultimately selling any products. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is sufficient to achieve profitability. Even if we do achieve profitability, we may not be able to sustain profitability or meet outside expectations for our profitability. If we are unable to achieve or sustain profitability or to meet outside expectations for our profitability, the price of our common stock could be materially adversely affected. Because of the numerous risks and uncertainties associated with biopharmaceutical and biotechnology products and drug development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the U. S. Food and Drug Administration (FDA) or comparable foreign regulatory authorities to perform studies in addition to those we currently anticipate, or if there are any delays in commencing or completing our clinical trials or the development of any of our product candidates, our expenses could increase and commercial revenue could be further delayed and become more uncertain, which will have a material adverse impact on our business. **Our substantial contingent consideration and related obligations from our acquisitions of assets and license and collaboration agreements may result in dilution to our stockholders, may be a drain on our cash resources, or may cause us to incur debt obligations to satisfy the payment obligations.** In connection with our acquisitions of assets in late 2020, we entered into arrangements whereby the former stockholders of those companies are entitled to substantial contingent consideration payments upon the occurrence of certain events. For example, in connection with our acquisition of BlackThorn Therapeutics, Inc. (BlackThorn), a privately held company, the former BlackThorn stockholders are entitled to contingent consideration (i) with respect to navacaprant (NMRA - 140), in the form of development and regulatory approval milestones of up to an aggregate amount of \$ 365. 0 million, which includes a milestone payment that became due in October 2023 upon dosing the first patient in the Phase 3 clinical trial for navacaprant, which was primarily settled by issuing unregistered shares of our common stock in December 2023, and sales - based milestones of up to an aggregate amount of \$ 450. 0 million and (ii) with respect to NMRA - 511, in the form of development and regulatory approval milestones of up to an aggregate amount of \$ 100. 0 million and sales - based milestones of up to an aggregate amount of \$ 100. 0 million (BlackThorn Milestone Payments). With the exception of one development milestone in the amount of \$ 10. 0 million that is required to be settled in cash, the remaining BlackThorn Milestone Payments may be settled in cash or shares of our equity, or a combination of both, at our sole discretion. In connection with the BlackThorn acquisition, we also became obligated under its license agreement with TSRI for, among other obligations, development and regulatory milestone payments of up to \$ 1. 5 million in aggregate for the first product from each of the TSRI programs and commercial milestone payments of up to \$ 3. 5 million in aggregate for each occurrence. Under the terms of our September 2021 license agreements with Amgen, we are obligated to pay Amgen up to an aggregate of \$ 720. 0 million in commercial milestone payments upon the achievement of certain sales thresholds and single digit royalties on potential annual worldwide net sales related to the CK1δ or GCase programs. In addition, under the collaboration agreement with Amgen, we committed to making quarterly payments to Amgen for their collaboration activities over three years totaling \$ 62. 5 million. Under the terms of our license agreement, as amended, with Vanderbilt University (Vanderbilt), we are obligated to pay Vanderbilt up to an aggregate of \$ 422. 4 million in development and commercial milestone payments upon the achievement of certain development milestones, which includes a milestone payment of \$ 2. 0 million that became due in October 2023, and sales thresholds, and mid - single digit royalties on potential future net sales. In order to satisfy our obligations to make these payments, if and when they are triggered, we may need to issue equity or convertible debt securities that may cause dilution to our stockholders, or we may use our existing cash or incur debt obligations to satisfy the payment obligations in cash, which may adversely affect our financial position. In addition, these obligations may impede our ability to raise money in future public offerings of debt or equity securities or to obtain a third - party line of credit. See the sections titled “ Management’ s Discussion and Analysis of Financial Condition and Results of Operations — Acquisitions of Assets ” and “ Management’ s Discussion and Analysis of Financial Condition and Results of Operations — Strategic License and Research and Collaboration Agreements ” in this Annual Report on Form 10- K for additional information regarding these agreements. **Our limited operating history may make it difficult to evaluate our prospects and likelihood of success.** We are a clinical - stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. Since our inception in November 2019, we have devoted substantially all of our resources and efforts to building our organization, acquiring technologies and companies, executing preclinical studies and clinical trials, conducting research and development, identifying and developing potential product candidates, building our precision neuroscience tools, organizing and staffing our company, business planning, establishing, maintaining and protecting our

intellectual property portfolio, raising capital and providing general and administrative support for these operations. All of our product candidates are in either clinical development or in preclinical stages of development, and we have not yet demonstrated our ability to successfully complete any late - stage or registrational / pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions you may make about our future success or viability may not be as accurate as they could be if we had a longer operating history. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical - stage biotechnology and biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, it could have a material adverse effect on our business. **We will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.** Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time - consuming, expensive and uncertain process that takes years to complete. We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek regulatory and marketing approval for, our product candidates. **If Even if** one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. To date, we have funded our operations principally through private financings. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the clinical and preclinical development of our product candidates, continue to develop and deploy our precision neuroscience approach, commence additional preclinical studies and clinical trials, and continue to identify and develop additional product candidates either through internal development or through acquisitions or in - licensing product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding in order to support our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future regulatory approval or commercialization efforts. We expect to continue to expend significant resources for the foreseeable future. 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. Attempting to secure additional financing may divert our management from our day - to - day activities, which may adversely affect our ability to develop our product candidates. Our future capital requirements will depend on many factors, including but not limited to: • the scope, timing, progress, costs and results of discovery, preclinical development and clinical trials for our current or future product candidates; • the number of clinical trials required for regulatory approval of our current or future product candidates; • the costs, timing and outcome of regulatory review of any of our current or future product candidates; • the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses; • the cost of manufacturing clinical and commercial supplies of our current or future product candidates; • the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property - related claims, including any claims by third parties that we are infringing upon their intellectual property rights; • the effectiveness of our precision neuroscience approach at identifying target patient populations and utilizing our approach to enrich our patient population in our clinical trials; • our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement; • our ability to access additional multimodal patient datasets; • the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval; • the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; • expenses to attract, hire and retain skilled personnel; • the costs of operating as a public company; • our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third - party and government payers; • the effect of macroeconomic trends including inflation, tariffs, and rising interest rates; • addressing any potential supply chain interruptions or delays; • the effect of competing technological and market developments; and • the extent to which we acquire or invest in business, products and technologies. Our ability to raise additional funds will depend on financial, economic, political and market conditions and other factors, over which we may have no or limited control. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, future commercialization efforts or other operations. Because of the numerous risks and uncertainties associated with research, product development and commercialization of product candidates, we are unable to predict the timing or amount of our working capital requirements or when or if we will be able to achieve or maintain profitability. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives and adequate additional financing may not be available to us on acceptable terms, or at all. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations with our existing cash, cash equivalents and marketable securities, the net proceeds from our initial public offering, any future equity or debt financings and upfront and milestone and royalties payments, if any, received under any future licenses or collaborations. If we raise additional capital through the sale of equity or convertible debt

securities, or issue any equity or convertible debt securities in connection with a collaboration agreement or other contractual arrangement, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. In addition, the possibility of such issuance may cause the market price of our common stock to decline. For example, in **October 2024 we entered into a sales agreement with Leerink Partners LLC (Leerink) to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to \$ 300. 0 million, through an at- the- market equity offering program (ATM) with Leerink as the sales agent. During the year ended December 31, 2024, we received aggregate net proceeds of \$ 13. 7 million through sales of shares of our common stock under the ATM after deducting commissions and offering expenses of \$ 0. 8 million. In**

December 2023, we settled a Phase 3 navacaprant milestone owed to Blackthorn stockholders by primarily issuing shares of our common stock. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring, selling or licensing intellectual property rights or assets, which could adversely impact our ability to conduct our business. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, operating results and prospects. We maintain the majority of our cash and cash equivalents in accounts with major U. S. and multi - national financial institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions and changes in financial regulations and policies can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. In addition, changes in regulations governing financial institutions are beyond our control and difficult to predict; consequently, the impact of such changes on our business and results of operations is difficult to predict and may have an adverse effect on us. Risks Related to Our Business **BusinessIf we are unable to successfully identify, develop and commercialize any product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.**

Our ability to generate revenue from sales of any of our approved product candidates, which we do not expect will occur for at least the next several years, depends heavily on the successful identification, development, regulatory approval and eventual commercialization of any product candidates, which may never occur. We have never generated revenue from sales of any products, and we may never be able to develop, obtain regulatory approval for, or commercialize, a marketable product. All of our product candidates will require significant clinical development, regulatory approval, establishment of sufficient manufacturing supply, including commercial manufacturing supply, and may require us to build a commercial organization and make substantial investment and significant marketing efforts before we generate any revenue from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. The successful development of our product candidates will depend on several factors, including, but not limited to, the following: • successful and timely completion of preclinical studies and clinical trials for which the FDA, or any comparable foreign regulatory authority, **agree-align** with the design, endpoints, or implementation; • sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials; • receiving regulatory approvals, allowances or authorizations for conducting future clinical trials; • initiation and successful patient enrollment in, and completion of, clinical trials on a timely basis; • our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe and effective as for its intended uses; • our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk - benefit ratio for its proposed indication is acceptable; • timely receipt of marketing approvals for our product candidates from applicable regulatory authorities; • **addressing any potential supply chain interruptions or delays;** • the extent of any required post - marketing approval commitments to applicable regulatory authorities; and • establishing, scaling up and scaling out, either alone or with third - party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which would materially adversely affect our business, financial condition, and results of operations. Additionally, clinical or regulatory setbacks to other companies developing similar products or within adjacent fields may impact the clinical development of and regulatory pathway for our current or future product candidates, or may negatively impact the perceptions of value or risk of our technologies. **We were founded with a mission to redefine neuroscience drug development, a field that has seen very limited success. The ability to successfully develop drugs in this field is extremely difficult and is subject to a number of unique challenges.** Drug development in the field of brain diseases, and neuropsychiatric disorders and neurodegenerative diseases in particular, has seen very limited success historically. We estimate over \$ 110 billion **have-has** been spent on neuroscience research and development since 2019 in the United States alone, representing approximately 33 % of all disease - specific spending. However, only approximately 12 % of all new therapies approved during this time period have been for the treatment of brain diseases. From 2011 to 2020, clinical development success rates for new drug candidates that employed patient selection biomarkers were approximately 16 % compared to approximately 8 % for patients without patient selection biomarkers according to the BIO; however, clinical success depends on a number of factors and employing a patient selection biomarker approach does not guarantee that our product candidates will be approved and commercialized. Developing a product candidate

for treatment of these brain diseases is extremely difficult and subjects us to a number of unique challenges, including obtaining regulatory approval from the FDA and other regulatory authorities who have only a limited set of precedents to rely on. We intend to work closely with the FDA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation in an effort to obtain regulatory approval for our product candidates; however, the process of developing our product candidates may be more complex and time-consuming relative to other more well-known approaches to drug development. We cannot be certain that our approach will lead to the development of product candidates that effectively and safely address the underlying brain diseases. Moreover, given the history of clinical failures in this field, future clinical or regulatory failures by us or others may ~~have~~ result in further negative perception of the likelihood of success in this field, which may significantly and adversely affect the market price of our common stock. **We have invested and expect to continue to invest in acquiring product candidates, technologies and assets, as well as research and development efforts that further enhance our product pipeline. Such investments may affect our operating results, and, if the return on these investments is lower or develops more slowly than we expect, our revenue and operating results may suffer.** We have invested and expect to continue to invest in acquiring potential product candidates to enhance our product pipeline, technologies and assets. These activities and investments involve significant time, risks, and uncertainties, including the risk that the associated expenses may affect our operating results, ~~that~~ such investments may not generate products that can be successfully developed or technologies that can be effectively used by us, and **may** cause significant drains on capital resources and commit us to substantial financial obligations. While we believe that we must continue to invest a significant amount of time and resources in the development of our product pipeline, if we do not achieve the benefits anticipated from these investments, or if the achievement of these benefits is delayed, our business, operating results and prospects may be materially adversely affected. **We have experienced rapid growth since our inception in November 2019. If we fail to effectively manage our growth, we may not be able to execute on our business objectives.** As of December 31, 2022-2024, we had 112-110 full-time employees and, as of December 31, 2023, we had grown to 124 full-time employees. We expect continued growth in the number of our employees and the scope of our operations, particularly as we continue our current and future clinical trials and preclinical studies, initiate and conduct investigational new drug application (IND)-enabling studies and build out our clinical operations, regulatory, quality and manufacturing infrastructure. In addition to headcount growth, we have made a number of acquisitions of assets, and entered into a significant strategic collaboration with Amgen and in-licensed programs from Amgen and Vanderbilt. These activities have added significant complexity to our organization, including a number of clinical and preclinical programs that we are now developing. These programs require significant infrastructure and headcount to effectively prosecute. To manage our anticipated future growth, we will continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to the complexity in managing a company that has scaled very quickly ~~and anticipates continued growth~~, we may not be able to scale our headcount and operations effectively to manage the expansion of our product pipeline or recruit and train the necessary additional personnel. ~~The expansion of our operations may lead to significant costs and may divert our management and business development resources.~~ Any inability to manage growth could delay the execution of our business plans or disrupt our operations. In addition, **any** future growth **would impose- impose** significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining, and motivating additional employees; managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and improving and scaling our operational, financial and management controls, reporting systems and procedures. We currently rely on certain independent organizations, advisors, and consultants to provide certain services, including strategic, financial, business development, and research and development services, as well as certain aspects of regulatory approval 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 consultants or contract manufacturing organizations is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on reasonable terms, or at all. Our ability to develop product candidates, leverage our precision neuroscience approach and our future growth depends on attracting, hiring and retaining our key personnel and recruiting additional qualified personnel. Our success depends upon the continued contributions of our key management and scientific personnel, many of whom have been instrumental for us and have substantial experience with developing therapies, identifying potential product candidates and building the technologies related to the clinical development of our product candidates. Given the specialized nature of brain diseases and our approach, there is an inherent scarcity of experienced personnel in these fields. As we continue developing our product candidates in our pipeline, we will require personnel with medical, scientific, or technical qualifications specific to each program. The loss of key personnel, in particular our neuroscientists, would delay our research and development activities. Despite our efforts to retain valuable employees, members of our team may terminate their employment with us on short notice. The competition for qualified personnel in the biotechnology and biopharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which would have a material adverse effect on our business. In addition, our clinical operations and research and development programs depend on our ability to attract and retain highly skilled scientists, data scientists, and engineers, particularly in Massachusetts and California. There is powerful competition for skilled personnel in these geographical markets, and we have from time to time

experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we do, and any of our employees may terminate their employment with us at any time. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed. We may not realize the benefits of assets that we have acquired, or will acquire in the future, or other strategic transactions that we have consummated or will consummate. Our approach represents an aggregation of innovation and assets from multiple companies and academic institutions, including BlackThorn, Syllable and Alairion as well as Amgen, TSRI and Vanderbilt. Further, a key component of our strategy is to acquire and in-license assets and technologies to support the growth of our product pipeline and to enhance our Precision Toolbox. As such, we actively evaluate various strategic transactions on an ongoing basis. We may acquire other assets, businesses, products or technologies, as well as pursue joint ventures or investments in complementary businesses. The success of our strategic transactions and any future strategic transactions depends on the risks and uncertainties involved including: • unanticipated liabilities related to acquired companies or joint ventures; • difficulties integrating acquired personnel, technologies, and operations into our existing business; • retention of key employees; • diversion of management time and focus from operating our business to the management of acquisition and integration efforts, strategic alliances or joint ventures challenges; • increases in our expenses and reductions in our cash available for operations and other uses; • disruption in our relationships with collaborators or suppliers; and • possible write-offs or impairment charges relating to acquired businesses or joint ventures. If any of these risks or uncertainties occur, we may not realize the anticipated benefit of any acquisition or strategic transaction. For example, less than one year following the acquisition of Propellex, we terminated and are no longer developing the program we acquired from Propellex. ~~We have ceased the development of our NMRA - 094 product candidate for the treatment of obstructive sleep apnea (OSA) that we acquired from Alairion based on pre-IND feedback we received from the FDA.~~ Additionally, foreign acquisitions and joint ventures are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political and regulatory risks associated with specific countries. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses, impairments or write-offs of goodwill or impairments and write-offs of in-process research and development assets, any of which could harm our financial condition. We have relied on, and in the future will continue to rely on, third-party datasets and databases to build and enhance our precision neuroscience approach. If we are not able to access additional data sets or develop enhancements to our precision neuroscience approach, our ability to execute on our strategy may be limited. Our ability to execute on our drug development strategy depends in part on our ability to enhance and improve our precision neuroscience approach. As part of this approach, we interrogate public, partnered and proprietary datasets across neuropsychiatric and neurodegenerative diseases, currently encompassing genetic, imaging, electroencephalogram (EEG), digital and clinical data. We rely on these datasets and data analytics for identifying or validating some of our biomarker-target relationships. The success of our precision neuroscience approach and any enhancement to our approach depends on several factors, including access to and generation of additional multimodal patient datasets, whether public, partnered or proprietary, development of more advanced proprietary machine learning capabilities and increased computational storage and processing capacity. If we are unable to access additional datasets or they are not available on acceptable terms, or if we are otherwise unsuccessful in enhancing our approach, we may be limited in our precision neuroscience capabilities and not be able to fully utilize a precision neuroscience drug development strategy. In addition, access to public data sets may be limited by governmental or other restrictions, including restrictions on commercial application by government or government sponsored organizations or privacy related restrictions. See the risk factor “ We face potential liability related to the privacy of health information we utilize in the development of product candidates, as well as information we obtain from clinical trials sponsored by us from research institutions and directly from individuals ” for additional information on privacy related considerations. **We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.** The biotechnology and biopharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop and obtain marketing approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large biopharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection and establish collaborative arrangements for research, development, manufacturing, and marketing of products that compete with our product candidates. Mergers and acquisitions in the biotechnology and biopharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. With the proliferation of new drugs and therapies for our target indications, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and biopharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical. Our competitors

may, among other things: • have significantly greater financial, manufacturing, marketing, drug development, technical, and human resources than we do; • develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe side effects; • obtain quicker regulatory approval; • establish superior proprietary positions covering our products and technologies; • implement more effective approaches to sales and marketing; or • form more advantageous strategic alliances. Should any of these factors occur, our business, financial condition and results of operations could be materially adversely affected. In addition, any collaborators may decide to market and sell products that compete with the product candidates that we have agreed to license to them, and any competition by our collaborators could also have a material adverse effect on our future business, financial condition, and results of operations. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in developing or acquiring technologies complementary to, or necessary for, our programs. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms, and product candidates that we identify for specific indications. Additionally, we have contractual commitments under the agreements for various product candidate assets that we acquired from third parties, as well as our license and collaboration agreements, to use commercially reasonable efforts to develop certain programs and, thus, do not have unilateral discretion to vary from such agreed to efforts. In addition, we have contractual commitments to conduct certain development plans, and thus may not have discretion to modify such development plans, including clinical trial designs, without agreement from our collaboration partner. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms, and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. We rely upon third-party providers of cloud-based infrastructure to host our platforms. Any disruption in the operations of these third-party providers, limitations on capacity, or interference with our use could adversely affect our business, financial condition, and results of operations. We outsource substantially all of the technological infrastructure relating to our hosted platform to third-party hosting services, such as Amazon Web Services. We have no control over any of these third parties, and while we attempt to reduce risk by minimizing reliance on any single third party or its operations, we cannot guarantee that such third-party providers will not experience system interruptions, outages or delays, or deterioration in their performance. We need to be able to access our computational platform at any time, without interruption or degradation of performance. Our hosted platform depends on protecting the virtual cloud infrastructure hosted by third-party hosting services by maintaining its configuration, architecture, features, and interconnection specifications, as well as protecting the information stored in these virtual data centers, which is transmitted by third-party Internet service providers. We have experienced and expect that in the future we may again experience interruptions, delays and outages in service and availability from time to time due to a variety of factors, including infrastructure changes, human or software errors, website hosting disruptions and capacity constraints. Any limitation on the capacity of our third-party hosting services could adversely affect our business, financial condition, and results of operations. In addition, any incident affecting our third-party hosting services' infrastructure that may be caused by cyber-attacks, natural disasters, fire, flood, severe storm, earthquake, power loss, telecommunications failures, terrorist or other attacks, and other disruptive events beyond our control could negatively affect our cloud-based solutions. A prolonged service disruption affecting our cloud-based solutions could damage our reputation or otherwise harm our business. We may also incur significant costs for using alternative equipment or taking other actions in preparation for, or in reaction to, events that damage the third-party hosting services we use. In the event that our service agreements with our third-party hosting services are terminated, or there is a lapse of service, elimination of services or features that we utilize, interruption of internet service provider connectivity, or damage to such facilities, we could experience interruptions in access to our platform as well as significant delays and additional expense in arranging or creating new facilities and services and / or re-architecting our hosted software solutions for deployment on a different cloud infrastructure service provider, which could adversely affect our business, financial condition, and results of operations. If our security measures are breached or unauthorized access to our other data is otherwise obtained, our data may be perceived as not being secure and we may incur significant liabilities. We use a set of proprietary tools to generate, analyze, and derive novel insights from our data. As a result, unauthorized access to or security breaches of our data, as a result of third-party action, employee or contractor error, malfeasance, or otherwise could require **us to make filings with the SEC and provide** notification to individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws and result in the loss or corruption of, or other damage to information, claims and litigation, indemnity obligations, damage to our reputation, and other liability. Our collaborators and other third parties we work with may also suffer similar security breaches of data that we rely on. Because the techniques used to obtain unauthorized access or sabotage systems change frequently and generally are not identified until they are launched against a target, we and those we collaborate with may be unable to anticipate these techniques or implement adequate preventative measures. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. In addition, if our employees or contractors fail to adhere to practices we have established to maintain a

firewall between our internal drug discovery team and our teams that work with external individuals, including our collaborators, or if the technical solutions we have adopted to maintain the firewall malfunction, our collaborators may lose confidence in our ability to maintain the confidentiality of their intellectual property, we may have trouble attracting new collaborators, we may be subject to breach of contract claims by our collaborators, and we may suffer reputational and other harm as a result. Federal, state and foreign laws and regulations may also expose us to enforcement actions and investigations by regulatory authorities, and potentially result in **legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, fines negative reputational impacts that cause us to lose existing or future customers, and / or significant legal liability incident response, if system restoration or information technology security efforts fail remediation and future compliance costs**. Any or all of these issues could result in reputational damage or subject us to third-party lawsuits or other action or liability, which could adversely affect our operating results and the further development and commercialization of our products. Our insurance may not be adequate to cover losses associated with such events, and in any case, such insurance may not cover all of the types of costs, expenses, and losses we could incur to respond to and remediate a security breach. Our precision neuroscience tools utilize third-party open source software, and any failure to comply with the terms of one or more of these open source software licenses could adversely affect our business, subject us to litigation, or create potential liability. Our precision neuroscience tools include software licensed by third parties under any one or more open source licenses, and we expect to continue to incorporate open source software in our precision neuroscience tools in the future. While we have a process in place for monitoring the use of open source software by our employees, we cannot ensure we are aware of every instance of such use or have validated the quality or source of such software, or that we are in compliance with the terms of the applicable open source licenses or our current policies and procedures. There have been claims against companies that use open source software in their products and services asserting that the use of such open source software infringes the claimants' intellectual property rights. As a result, we could be subject to suits by third parties claiming that what we believe to be licensed open source software infringes such third parties' intellectual property rights. Additionally, if an author or other third party that distributes such open source software were to allege that we had not complied with the conditions of one or more of these licenses, we could be required to incur significant legal expenses defending against such allegations and could be subject to significant damages and required to comply with onerous conditions or restrictions on these solutions, which could disrupt the distribution and sale of these solutions. Litigation could be costly for us to defend, have a negative effect on our business, financial condition, and results of operations, or require us to devote additional research and development resources to change our precision neuroscience tools. Furthermore, these third-party open source providers could experience service outages, data loss, privacy breaches, cyber-attacks, and other events relating to the applications and services they provide that could diminish the utility of these services and which could harm our business as a result. Use of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code, including with respect to security vulnerabilities where open source software may be more susceptible. In addition, certain open source licenses require that source code for software programs that interact with such open source software be made available to the public at no cost and that any modifications or derivative works to such open source software continue to be licensed under the same terms as the open source software license. The terms of various open source licenses to which we are subject have not been interpreted by courts in the relevant jurisdictions, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to market or provide our software and data. By the terms of certain open source licenses, we could be required to release the source code of our proprietary software, and to make our proprietary software available under open source licenses, if we combine our proprietary software with open source software in a certain manner. In the event that portions of our proprietary software are determined to be subject to an open source license, we could be required to publicly release the affected portions of our source code, re-engineer all or a portion of our precision neuroscience tools, or otherwise be limited in the licensing of our precision neuroscience tools, each of which could reduce or eliminate the value of our precision neuroscience tools. Disclosing our proprietary source code could allow our competitors to create similar products with lower development effort and time and ultimately could result in a loss of sales. Furthermore, any such re-engineering or other remedial efforts could require significant additional research and development resources, and we may not be able to successfully complete any such re-engineering or other remedial efforts. Any of these events could create liability for us and damage our reputation, which could have a material adverse effect on our revenue, business, results of operations, and financial condition and the market price of our shares. Risks Related to the Development and Clinical Testing of Our Product **CandidatesClinical and preclinical drug development is a lengthy and expensive process, with an uncertain outcome. Our clinical and preclinical programs have experienced delays and may experience additional delays or may never advance, which would adversely affect our ability to obtain regulatory approvals or commercialize our product Candidates candidates on a timely basis or at all, which could have an adverse effect on our business.** In order to obtain FDA approval to market our product candidates, we must demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the FDA. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Clinical testing is expensive, time-consuming and subject to uncertainty. Conducting preclinical testing and clinical trials represents a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting preclinical studies may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, but not limited to: • inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical studies; • timely completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's Good Laboratory Practice (GLP) requirements and other applicable regulations; • approval by an independent Institutional Review

Board (IRB) or ethics committee at each clinical site before each trial may be initiated; • delays in reaching a consensus with regulatory agencies on study design and obtaining regulatory authorization to commence clinical trials; delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; • delays in identifying, recruiting and training suitable clinical investigators; • delays in recruiting suitable patients to participate in our clinical trials; • delays in manufacturing, testing, releasing, validating or importing / exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing; • insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials; • imposition of a temporary or permanent clinical hold by regulatory authorities; • developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives; • delays in recruiting, screening and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up; • difficulty collaborating with patient groups and investigators; • failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practice (GCP) requirements, or applicable regulatory guidelines in other countries; • occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies; • changes to the clinical trial protocols; • clinical sites deviating from trial protocol or dropping out of a trial; • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; • changes in the standard of care on which a clinical development plan was based, which may require new or additional trials; • selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; • the cost of clinical trials of our product candidates being greater than we anticipate; • clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates; • transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization (CMO) and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and • third parties being unwilling or unable to satisfy their contractual obligations to us. Clinical trials must be conducted in accordance with the FDA's and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where the clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable 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 comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, **nonclinical safety pharmacology studies in April 2024, our Phase 1 trial of NMRA - 266 was placed on - 511 indicate that the dose limiting toxicities were CNS observations including tremor and convulsions, which led to a partial clinical hold on our IND by the FDA after data from nonclinical studies showed convulsions in rabbits. Although we are in discussions with the FDA regarding the potential to remove the clinical hold, there is no guarantee that was removed when we amended the protocol will be able to include tremors as a stopping criterion successfully resolve the clinical hold issues or resume clinical studies of NMRA- 266 in the time and manner that we expect**. 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 for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority 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 or comparable foreign regulatory authority 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 or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates. Delays in the completion of any preclinical studies or clinical trials of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to our preclinical studies or clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business,

financial condition and prospects significantly. In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For **example instance**, 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 clinical trial application (CTA), to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. 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. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR ~~foresees a three-year transition period~~ **ended on**. ~~The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date,~~ **and all clinical trials (including those which and related applications) are now fully ongoing) will become** subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as Contract research organizations (CRO), may impact our development plans. It is currently unclear to what extent the UK will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency (MHRA), launched an eight-week consultation on reframing the UK legislation for clinical trials **which aimed to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials**. The **MHRA UK Government** published its **response to the consultation outcome** on March 21, 2023 confirming that it would bring forward changes to the legislation. These resulting legislative amendments, **which are yet to be published**, will **ultimately determine how closely the extent to which** the UK regulations ~~are aligned--~~ **align** with the **(EU) CTR**. A decision by the UK not to closely align its regulations with the new approach adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries. 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. Results of preclinical studies or clinical trials of any product candidates may not be predictive of the results of future preclinical studies or clinical trials. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we or any collaborator for such product candidate must demonstrate through extensive preclinical studies and clinical trials that the product candidate is safe and effective in humans. Before an IND can be submitted to the FDA and become effective, which is a prerequisite for conducting clinical trials on human subjects in the United States, a product candidate must successfully progress through extensive preclinical studies, which include preclinical laboratory testing, animal studies, and formulation studies, certain of which must be conducted in accordance with GLP. We cannot be certain of the timely completion or outcome of any preclinical studies. We also cannot predict if the FDA or comparable regulatory authorities will allow our proposed clinical programs to proceed or if the outcome of our preclinical studies will ultimately support further development of our programs. Additionally, we cannot be sure that we will be able to submit INDs or similar applications with respect to our product candidates on the timelines we expect, if at all, and we cannot be sure that submission of IND or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. Moreover, success in preclinical studies or early clinical trials does not ensure that later preclinical studies or clinical trials will be successful. A number of companies in the biotechnology and biopharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In addition, clinical and preclinical data are often susceptible to varying interpretations and analyses. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. **For example, in January 2025, we announced that our KOASTAL- 1 study did not demonstrate a statistically significant improvement on the primary endpoint of change from baseline in the Montgomery- Åsberg Depression Rating Scale (MADRS) total score at Week 6 or the key secondary endpoint of a change from baseline in the Snaith- Hamilton Pleasure Scale (SHAPS) scale**. In addition, the results of our preclinical animal studies, including our non-human primate studies, may not be predictive of the results of outcomes in subsequent clinical trials on human subjects. Product candidates in clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies. If we fail to receive positive results in preclinical studies or clinical trials of any product candidate, the development timeline and regulatory approval and commercialization prospects for that product candidate, and, correspondingly, our business and financial prospects, would be negatively impacted. Our product candidates may have serious adverse, undesirable, or unacceptable side effects or other properties that may delay or prevent marketing approval. If such side effects are identified following approval, if any, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a

more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. The drug - related side effects could 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. Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk - benefit perspective, which may limit the commercial expectations for the product candidate if approved. We may also be required to modify our study plans based on findings in our ongoing preclinical studies or clinical trials. For example, in a rat study, at its highest dose (100 mg / kg / day) navacaprant was observed to have skin - related phototoxicity of erythema, edema and flaking additionally ocular phototoxicity (corneal edema). While no phototoxicity has been observed in our Phase 1 clinical trials, we monitored visual acuity and corneal integrity in our Phase 2 clinical trial to confirm there was no phototoxicity in humans. Though we did not observe any phototoxicity effects in our Phase 2 clinical trial, if phototoxicity is experienced in our later - stage clinical trials, the labeling implications of such safety warnings may limit any future product sales, if navacaprant is approved. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, may be reported by subjects. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly. In the event that any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw or limit approvals of such products and require us to take our approved product off the market; • regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies, or issue other communications containing warnings or other safety information about the product; • regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy (REMS), plan to ensure that the benefits of the product outweigh its risks; • we may be required to change the dose or the way the product is administered, conduct additional clinical trials, or change the labeling of the product; • we may be subject to limitations on how we may promote or manufacture the product; • sales of the product may decrease significantly; • we may be subject to litigation or product liability claims; and • our reputation may suffer. Any of these events could prevent us or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of any products. Interim, topline, or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available or as we make changes to our manufacturing processes and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then - available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our ~~vaccine~~ **product** candidates may be harmed, which could harm our business, prospects, financial condition or results of operations. We ~~will~~ depend on enrollment and retention of patients in our clinical trials for our product candidates. If we experience delays or difficulties enrolling or retaining patients in our clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected. Successful and timely completion of clinical trials ~~will require~~ **requires** that we enroll and retain a sufficient number of patient candidates. Any clinical trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal or adverse events. These types of developments could cause us to delay the trial or

halt further development. Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. The eligibility criteria of our clinical studies, and in particular, any eligibility criteria we may establish using our precision neuroscience approach, may limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study. Patient enrollment depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process, and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. The estimates of market opportunity and forecasts of market growth included in our public disclosures may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all. We intend to initially focus our product candidate development on treatments for various neuropsychiatric disorders and neurodegenerative diseases. Our projections of addressable patient populations within any particular disease state that may benefit from treatment with our product candidates are based on our estimates. Market opportunity estimates and growth forecasts included in our public disclosures are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business. Even if approved, our products may not gain market acceptance, in which case we may not be able to generate product revenues, which will materially adversely affect our business, financial condition, and results of operations. Even if the FDA or any comparable foreign regulatory authority approves the marketing of any product candidates that we develop, physicians, healthcare providers, patients, or the medical community may not accept or use them. Additionally, the product candidates that we are developing are based on our proprietary approach, which are new technologies. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of any of our product candidates will depend on a variety of factors, including:

- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- the terms of any approvals and the countries in which approvals are obtained;
- the number and clinical profile of competing products;
- the potential and perceived advantages of our product candidates over alternative treatments;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- the availability of an approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- the effectiveness of sales and marketing efforts;
- approval of other new therapies for the same indications;
- marketing and distribution support;
- adverse publicity about our product candidates;
- availability of coverage, adequate reimbursement and sufficient payment from health maintenance organizations and other insurers, both public and private, for our product candidates, or the procedures utilizing our product candidates, if approved;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities; and
- other potential advantages over alternative treatment methods.

If our product candidates fail to gain market acceptance, this will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Even if some products achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues. We currently have no marketing, sales, or distribution infrastructure and we intend to either establish a sales and marketing infrastructure or outsource this function to a third party. Either of these commercialization strategies carries substantial risks to us. Given our stage of development, we currently have no marketing, sale, and distribution capabilities. If any of our product candidates complete clinical development and are approved, we intend to either establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates **in a legally compliant manner**, or to outsource this function to a third party. There are risks involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our

products or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator's business strategy. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, 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, which would have a material adverse effect on our business, financial condition, and results of operations. We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims. We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of biopharmaceutical products. While we currently have no products that have been approved for commercial sale, the future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. Even successful defense against product liability claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our product candidates; injury to our reputation; withdrawal of clinical trial participants; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management's time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any product candidate; and a decline in our share price. Although we maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may be unable to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims, and our business operations could be impaired.

Risks Related to Our Regulatory Environment

The development and commercialization of drug products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates on a timely basis if at all, our business will be substantially harmed. The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to our product candidates are subject to extensive regulation. In the United States, obtaining marketing approval for a new drug requires the submission of a New Drug Application (NDA) to the FDA, and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the NDA for that product candidate. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing, and controls. Outside the United States, many comparable foreign regulatory authorities employ similar approval processes. We have not previously submitted an NDA to the FDA or similar marketing application to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will receive regulatory approval. Obtaining approval of an NDA can be a lengthy, expensive, and uncertain process, and as a company we have no experience with the preparation of an NDA submission or any other marketing application. In addition, the FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as 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. Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, or regulatory authorities may not accept a submission due to, among other reasons, the content or formatting of the submission;
- the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities or those of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. The FDA and comparable

foreign regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any of our product candidates. For example, regulatory authorities in various jurisdictions have in the past had, and may in the future have, differing requirements for, interpretations of and opinions on our clinical and preclinical data. As a result, we may be required to conduct additional preclinical studies, alter our proposed clinical trial designs, or conduct additional clinical trials to satisfy the regulatory authorities in each of the jurisdictions in which we hope to conduct clinical trials and develop and market our products, if approved. Further, even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any comparable foreign regulatory authority. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post - marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. Furthermore, FDA and 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 proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) 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 impact on the pharmaceutical industry and our business in the long term. Even if our product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products. If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, testing, safety, efficacy, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post - marketing information and reports, **and** registration, as well as continued compliance with current good manufacturing practices (cGMPs) and similar foreign requirements, and GCPs for any clinical trials that we conduct post - approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post - marketing testing, including Phase 4 clinical trials, and additional surveillance to monitor the safety and efficacy of the product candidate. Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP and similar foreign regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, quality control, and distribution. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things: **•** issue warning letters or untitled letters; **•** issue, or require us to issue, safety - related communications, such as safety alerts, field alerts, "Dear Doctor" letters to healthcare professionals, or import alerts; **•** impose civil or criminal penalties; **•** suspend, limit, or withdraw regulatory approval; **•** suspend any of our preclinical studies and clinical trials; **•** refuse to approve pending applications or supplements to approved applications; **•** impose restrictions on our operations, including closing our and our contract manufacturers' facilities; or **•** seize or detain products, refuse to permit the import or export of products, or require us to conduct a product recall. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products, if approved. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Moreover, the policies of the FDA and of comparable foreign regulatory authorities 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 or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off - label uses. If we are found or alleged to have improperly promoted off - label uses, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about drug products. These regulations include standards and restrictions for direct - to - consumer advertising, industry - sponsored scientific and educational activities, promotional activities involving the internet and off - label promotion. For example, any regulatory approval that the FDA grants is limited to those indications and patient populations for which a drug is deemed to be safe and effective by the FDA.

While physicians in the United States may choose, and are generally permitted, to prescribe products in their independent medical judgment for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote any of our products candidates, if approved, will be narrowly limited to those indications and populations that are specifically approved by the FDA or such other regulatory agencies, and if we are found to have promoted such off - label uses, we may become subject to significant liability. For example, the federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off - label promotion. The government has also required companies to enter into consent decrees or imposed 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. Disruptions at the FDA and other government agencies caused by funding shortages, **staffing reductions** or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, **reductions in staffing**, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, **in recent over the last several** years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, during the COVID - 19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points - ~~Even though, **and more recently the there have been** FDA **staff cuts under the Trump** has resumed standard inspection operations of domestic facilities where feasible, and any resurgence of COVID - 19 or emergence of new variants may lead to further inspectional or administrative **administration** delays.~~ If a prolonged government shutdown occurs, or if **staffing reductions or** global health concerns ~~continue to~~ prevent the FDA or other regulatory authorities from conducting their regular activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti - corruption laws, and anti - money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, various economic and trade sanctions regulations administered by the U. S. Treasury Department's Office of Foreign Assets Controls, the U. S. Foreign Corrupt Practices Act of 1977, as amended (FCPA), the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and other state and national anti - bribery and anti - money laundering laws in the countries in which we conduct activities. Anti - corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government - affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing. Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed, or become more expensive. Our business operations and current and future relationships with healthcare professionals, principal investigators, consultants, vendors, customers, and third - party payors in the United States and elsewhere are subject to applicable anti - kickback, fraud and abuse, false claims, physician payment transparency, and other healthcare laws and regulations, which could expose us to substantial penalties, contractual damages, reputation harm, administrative burdens, and diminished profits. Healthcare providers, healthcare facilities and institutions and third - party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, healthcare facilities and institutions, principal investigators, consultants, customers, and third - party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti - Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we research, sell, market, and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and regulation by the federal government and by the states and foreign

jurisdictions in which we conduct our business. The applicable federal, state, and foreign healthcare laws that affect our ability to operate include, but are not limited to, the following:

- the federal Anti - Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U. S. federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U. S. federal civil and criminal false claims laws, including the civil False Claims Act, which prohibit, among other things, including through civil whistleblower or qui tam actions, individuals or entities from knowingly presenting, or causing to be presented, to the U. S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the U. S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U. S. federal government by, among other things, engaging in impermissible marketing practices, such as the off - label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti - Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items, or services. Similar to the federal Anti - Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- the U. S. Physician Payments Sunshine Act and its implementing regulations, which requires, among other things, certain manufacturers of drugs and devices that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members;
- analogous U. S. state laws and regulations, including: state anti - kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by any third - party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U. S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and
- similar healthcare laws and regulations in foreign jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of our product candidates, if approved. Compensation under some of these arrangements includes the provision of stock or stock options in addition to cash consideration. Because of the complex and far - reaching nature of these laws, it is possible that governmental authorities could conclude that our payments to physicians may not be fair market value for bona fide services or that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, exclusion from government - funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of noncompliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time - consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other misconduct. We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we

operate, including, without limitation, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition, and patient privacy and other privacy laws and regulations. Misconduct by employees could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, labeling, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain. In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of the ACA of importance to the biopharmaceutical and biotechnology industries are the following: • manufacturers and importers of certain branded prescription drugs are required to pay an annual, nondeductible fee according to their market share of all such sales; • an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1 % of the average manufacturer price for most branded drugs, and to 13.0 % for generic drug; • a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs, including our product candidates, that are inhaled, infused, instilled, implanted, or injected; • extension of manufacturers' Medicaid rebate liability to covered outpatient drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; • expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133 % of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; • expansion of the entities eligible for discounts under the 340B drug pricing program; • a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and • establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA remains in effect in its current form. ~~Prior to the Supreme Court's decision, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.~~ On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the IRA) into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. It is unclear how other healthcare reform measures of the ~~Biden~~ **Biden-Trump** administration or other efforts, if any, to challenge, repeal or replace the ACA, will impact our business. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100 % of a drug's average manufacturer price. Further, in August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional action is taken by Congress. Moreover, heightened governmental scrutiny is likely to continue over the manner in which manufacturers set prices for their marketed products, which already has resulted in several Congressional inquiries, proposed and enacted legislation and executive orders issued by the President designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Most recently, the IRA

marks the most significant action by Congress with respect to the biopharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), 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 which began on January 1, 2025). Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29-15, 2023-2024, HHS announced the list of agreed upon prices for the first ten drugs that are will be subject to price negotiations, although which take effect in January 2026. HHS will select up to fifteen additional products covered under Part D for negotiation in 2025. Each year thereafter, more Part B and Part D products will become subject to the HHS Medicare drug-price negotiation program, although the program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated, and while the impact of the IRA on the biopharmaceutical industry cannot yet be fully determined, it is likely to be significant. Additionally, individual states in the United States have passed legislation and implemented regulations designed to control biopharmaceutical product pricing and costs. Similar developments have occurred outside of the United States, including in the European Union where healthcare budgetary constraints have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. To obtain reimbursement or pricing approval in some European Union member states, we may be required to conduct studies that compare the cost-effectiveness of our product candidates to other therapies that are considered the local standard of care. We cannot predict the likelihood, nature, or extent of government regulation that may arise from the IRA or future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. Even if we are able to commercialize any product candidate, coverage and adequate reimbursement may not be available or such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business. The regulations that govern regulatory approvals, pricing, and reimbursement for drug products vary widely from country to country. Some countries require approval of the sale price of a drug product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription drug product pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval. Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, such as government authorities, private health insurers, and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the relatively early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of coverage and reimbursement. Increasingly, the third-party payors who reimburse patients or healthcare providers are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for drug products. If the price we are able to charge for any products we develop, or the coverage and reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be affected adversely. There may be significant delays in obtaining reimbursement for newly-approved drug products, and coverage may be more limited than the purposes for which the drug product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drugs product will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drug products, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drug products that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drug products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of drug products from countries where they may be sold at lower prices than in the United States. Obtaining coverage and adequate reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. There have been, and likely will continue to

be, legislative and regulatory proposals at the foreign, federal, and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: • the demand for our product candidates, if we obtain regulatory approval; • our ability to set a price that we believe is fair for our products; • our ability to obtain coverage and reimbursement approval for a product; • our ability to generate revenue and achieve or maintain profitability; • the level of taxes that we are required to pay; and • the availability of capital. Our inability to promptly obtain coverage and adequate reimbursement from both third - party payors for the product candidates that we may develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations, and prospects. We face potential liability related to the privacy of health information we utilize in the development of product candidates, as well as information we obtain from clinical trials sponsored by us from research institutions and directly from individuals. The global data protection landscape is rapidly evolving and we and our partners and vendors are, or may become, subject to various federal, state, and foreign data protection laws and regulations (i. e., laws and regulations that address personal information, data privacy and security). Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. If we fail to comply with these laws and regulations, we may be subject to litigation, regulatory investigations, enforcement notices, enforcement actions, fines, and criminal or civil penalties, as well as adverse publicity and a potential loss of business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health - related and other personal information could apply to our operations or the operations of our partners. For example, most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009. HIPAA imposes obligations on “ covered entities, ” including certain healthcare providers, health plans and healthcare clearinghouses, as well as their respective “ business associates ” that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. We could potentially face substantial criminal or civil penalties if we violate HIPAA. For example, we could be subject to significant penalties if we knowingly receive individually identifiable health information from a HIPAA - covered healthcare provider or research institution that has not satisfied HIPAA’ s requirements for disclosure of individually identifiable health information, or otherwise violate applicable HIPAA requirements related to the protection of such information. Furthermore, the Federal Trade Commission (FTC) also has authority to initiate enforcement actions against entities that mislead customers about HIPAA compliance, make deceptive statements about privacy and data sharing in privacy policies, fail to limit third- party use of personal health information, fail to implement policies to protect personal health information or engage in other unfair practices that harm customers or that may violate Section 5 of the FTC Act. Even when HIPAA does not apply, according to the ~~Federal Trade Commission (FTC)~~ violating consumers’ privacy rights or failing to take appropriate steps to keep consumers’ personal information secure may constitute a violation of the FTC Act. The FTC expects a company’ s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Additionally, federal and state consumer protection laws are increasingly being applied by FTC and states’ attorneys general to regulate the collection, use, storage, and disclosure of personal or personally identifiable information, through websites or otherwise, and to regulate the presentation of website content. ~~We~~ For our clinical trials, we may maintain **certain** sensitive personal information **about individuals**, including health **- related** 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 enroll in our patient assistance programs. As such, we may be subject to state laws and regulations governing the privacy and security of personal information or requiring notification of affected individuals and state regulators in the event of a breach of personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act, **as amended by the California Privacy Rights Act (collectively, the CCPA) requires covered businesses that process** ~~went into effect on January 1, 2020, which establishes additional data privacy rights for residents of the State~~ **personal information** of California. The CCPA gives California residents **expanded rights to access, among other things: (i) provide certain disclosures to California residents regarding the business’ s collection, use, and delete disclosure of their personal information ; (ii) opt out of certain personal information sharing, and receive detailed information about how and respond to requests from California residents to access, delete, and correct their personal information is used. The CCPA, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers** ~~for civil penalties for violations, as well as a private right of action for data breaches that has increased~~ **process California resident personal information on the business’ s behalf** ~~likelihood of, and risks associated with, data breach litigation.~~ Although there are limited exemptions for health - related information, including clinical trial data, the CCPA may increase our compliance costs and potential liability . ~~Further, the California Privacy Rights Act (CPRA) generally went into effect on January 1, 2023, and significantly amends the CCPA. The CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for~~

higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required. Similar laws have been passed in other states, and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. Complying with U. S. federal and state data privacy and security laws, regulations, amendments to or re - interpretations of existing data privacy and security laws and regulations and contractual or other obligations relating to privacy, data protection, data transfers, data localization or information security may require us to make changes to our processes, incur substantial operational costs, modify our data practices and policies and restrict our business operations. Any actual or perceived failure by us to comply with these laws, regulations or other obligations may lead to significant fines, penalties, regulatory investigations, lawsuits, significant costs for remediation, damage to our reputation or other liabilities. We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. Any clinical trial programs and research collaborations that we engage in outside the United States may implicate international data protection laws, including, in the European Economic Area (EEA), the General Data Protection Regulation (GDPR), which became effective in 2018. The GDPR imposes stringent operational requirements for processors and controllers of the personal data of individuals within the EEA. Among other things, the GDPR requires detailed notices for clinical trial subjects and investigators, as well as requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects. If our privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices, and/or enforcement actions requiring us to change the way we use personal data and / or fines. In addition to statutory enforcement, a personal data breach can lead to adverse publicity and a potential loss of business. Further, from January 1, 2021, companies have had to comply with both the GDPR and the United Kingdom GDPR (UK GDPR), which, together with the amended UK Data Protection Act 2018, imposes separate but similar obligations to those under the GDPR. The UK GDPR mirrors the fines under the GDPR, imposing fines up to the greater of € 20 million (£ 17. 5 million) or 4 % of global turnover. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. Case law from the Court of Justice of the European Union (CJEU) states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case - by - case basis. **On July 10 President Biden signed an Executive Order on October 7, 2022 2023 , on ‘ Enhancing Safeguards for United States Signals Intelligence Activities’ which introduced new redress mechanisms and binding safeguards to address the concerns raised by the CJEU. European Commission adopted its Adequacy Decision** in relation to data transfers from the EEA to the United States and which formed the basis of the new EU -- US Data Privacy Framework (DPF) , as released on December 13, 2022. The European Commission adopted its Adequacy Decision in relation to the DPF on July 10, 2023, rendering the DPF effective as an EU GDPR transfer mechanism to U. S. entities self - certified under the DPF. On October 12, 2023, the UK Extension to the DPF also came into effect (as approved by the UK Government), as a UK GDPR data transfer mechanism to U. S. entities self - certified under the UK Extension to the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints, and / or regulatory investigations or fines, and / or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. These laws and regulations may apply, not only to us, but also to vendors that store or otherwise process data on our behalf, such as information technology vendors. If such a vendor misuses data we have provided to it, or fails to safeguard such data, we may be subject to litigation, regulatory investigations, enforcement notices, and / or enforcement actions, as well as adverse publicity and a potential loss of business. We are likely to 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. Moreover, even if we take all necessary action to comply with regulatory requirements, we could be subject to a hack or data breach, which could subject us to fines and penalties, as well as reputational damage. **Further** Although we work to comply with applicable laws , regulations and standards, our contractual obligations and other legal obligations; these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. If we fail to comply with applicable federal, state, local, or foreign regulatory requirements, we could be subject to a range of regulatory actions, including penalties and fines, that may also impact our compliance with contracts entered into with our partners, and that could affect our or any collaborators’ ability to seek to commercialize our clinical candidates. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used - **use** in other aspects of **artificial intelligence (AI), machine learning, and automated decision- making technologies (collectively, AI Technologies) throughout** our business. **The** Further, the regulatory framework for AI **Technologies /ML** automated decision making is evolving, and we may not always be able to anticipate how to respond to these laws or regulations given they are still rapidly evolving . There is **as many federal, state and foreign government bodies and agencies have**

introduced or are currently considering additional increase in litigation in a number of jurisdictions, including the United States, relating to the use of AI. New laws regulating AI are at an advanced stage of the legislative process in the EU, and it is possible that new laws and regulations will be adopted in the United States and in other non-U. **Additionally S. jurisdictions, or that existing laws and regulations may be interpreted in ways that would affect the way operation of our AI Technologies. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or market perception of their requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations. Already, certain existing legal regimes (e. g., relating to data privacy) regulate certain aspects of AI Technologies, and new laws regulating AI Technologies are expected to enter into force in the United States and the EU in 2024. In the United States, the Biden administration issued a broad Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (2023 AI Order), that sets out principles intended to guide AI design and deployment for the public and private sector and signals the increase in governmental involvement and regulation over AI Technologies. The 2023 AI Order established certain new requirements for the training, testing and cybersecurity of sophisticated AI models and large scale computer centers used to train AI models. The 2023 AI Order also instructed several other federal agencies to promulgate additional regulations within specific timeframes from the date of the 2023 AI Order regarding the use and development of AI Technologies. Agencies such as the Department of Commerce and the Federal Trade Commission have issued proposed rules governing the use and development of AI Technologies. Legislation related to AI Technologies has also been introduced at the federal level and is advancing at the state level. For example, on March 13, 2024, Utah passed the Utah AI Policy Act, which we took effect in May 2024, imposing certain disclosure requirements on the use of AI /ML, and on May 17, 2024, Colorado enacted the Colorado AI Act, which will take effect in February 2026 . Further, the cost to comply with such laws or California Privacy Protection Agency is currently in the process of finalizing regulations, or under the CCPA regarding the use of automated decisions- decision and/- making. Such additional regulations may impact or our ability to develop guidance interpreting existing laws, use could be significant and commercialize AI Technologies in the future would increase our operating expenses, which could adversely affect our business, financial condition and results of operations. In Europe, on April-May 21, 2021-2024 , the European Commission proposed a regulation seeking to Union legislators approved the EU Artificial Intelligence Act (the “ EU AI Act ”), which establish establishes a comprehensive, risk- based governance framework for AI artificial intelligence in the EU market (-. The EU AI Act) entered into force on August 2, 2024 and the majority of the substantive requirements will apply from August 2, 2026 . The proposal is intended to EU AI Act will apply to companies that develop, use and / or provide AI in the EU and includes requirements around transparency, conformity assessments and monitoring, risk assessments, human oversight, security and, accuracy , general purpose AI and foundation models , and proposes fines for breach of up to 6-7% of worldwide annual turnover. In addition, on September 28, 2022, the European Commission proposed two Directives seeking to establish a harmonized civil liability regime for AI in the EU . These regulatory proposals are at varying stages in order to facilitate civil claims in respect of the legislative process harm caused by AI and are not yet finalized; to include AI- enabled products within the scope of the EU’ s existing strict product liability regime. Once fully applicable, the EU AI Act is at an and advanced stage and the Liability Directives will text is currently expected to be finalized in 2024. Once finalized and in force, this regulatory framework is expected to have a material impact on the way AI is regulated in the EU -, Recent case law from the CJEU has taken and- an expansive view of the scope of the GDPR’ s requirements around automated decision making and introduced uncertainty in the interpretation of these rules. The EU AI Act, and developing interpretation and application of the GDPR in respect of automated decision making, together with developing guidance and / or decisions in this area, may affect our use of AI Technologies and our ability to provide, improve or commercialize our services business , require additional compliance measures and changes to our operations and processes, result in increased compliance costs and potential increases in civil claims against us, and could adversely affect our business, operations and financial condition. It is possible that further new laws and regulations will be adopted in the United States and in other non- U. S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of our business and the way in which we use AI Technologies. We may need to expend resources to adjust our operations in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions and / or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.**

Risks Related to Our Dependence on Third Parties-Parties We We contract with third parties for the manufacture of our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs 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. Furthermore, while the raw materials for our product candidates are sourced from multiple suppliers, in some cases, the drug product is sourced from a single - source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future 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 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, 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 third - party contractors to comply with applicable regulatory requirements; • the failure of the third party to manufacture our product candidates according to our specifications; • the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study 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, and are dependent on, our contract manufacturing partners for compliance with cGMP or similar foreign regulations for manufacturing both active drug substances and finished drug products. Third - party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or a comparable foreign regulatory authority, 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 or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. 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. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis. **In January 2024, there was congressional activity, including the introduction of the BIOSECURE Act (H. R. 7085) in the House of Representatives and a substantially similar Senate bill (S. 3558). The BIOSECURE Act was passed by the House of Representatives in September 2024. If these bills become law, or similar laws are passed, they would have the potential to severely restrict the ability of U. S. biopharmaceutical companies like us to purchase products or services from, or otherwise collaborate with, certain Chinese biotechnology companies “ of concern ” without losing the ability to contract with, or otherwise receive funding from, the U. S. government. It is possible some of our contractual counterparties, including WuXi AppTech and WuXi Biologics and other Chinese vendors, could be impacted by the legislation.** Supply sources could be interrupted from time to time and, if interrupted, there is no guarantee that supplies could be resumed within a reasonable time frame and at an acceptable cost or at all. We rely on our manufacturers to purchase from third - party suppliers the materials necessary to produce our product candidates for our preclinical studies and intend to continue to rely on these third parties for any clinical trials that we undertake. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our preclinical studies, clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event a new supplier must be used. The time and effort to qualify a new supplier could result in additional costs, diversion of resources, or reduced manufacturing yields, any of which would negatively impact our operating results. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third - party manufacturer could considerably delay completion of our clinical trials, product testing, and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed. We do not currently have the ability to independently conduct any clinical trials. We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third - party CROs, to conduct our preclinical studies

and clinical trials and to monitor and manage data for our clinical and preclinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third - party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations (or similar regulatory requirements outside of the United States). Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, that they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third - party service providers may require us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors, or if we are liquidated. Further, some of these agreements may also be terminated by such third parties on short notice, or under certain circumstances, including our insolvency. There is a limited number of third - party service providers that specialize or have the expertise required to achieve our business objectives. Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If any of our relationships with these third - party laboratories, CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, CROs, or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, CROs, or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements or for other reasons, our preclinical or clinical trials may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed. Switching or adding additional laboratories or CROs (or investigators) involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory or CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our contracted laboratories and CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects. ~~We may not realize the benefits of any collaborative or licensing arrangement, and if we fail to enter into new strategic relationships our business, financial condition, commercialization prospects, and results of operations may be materially adversely affected. Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. Therefore, for some of our product candidates, we may in the future decide to enter into collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate collaborators. Collaborations are complex and time - consuming to negotiate and document. We may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If our strategic collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. Moreover, our estimates of the potential revenue we are eligible to receive under any strategic collaborations we may enter into may include potential payments related to therapeutic programs for which our collaborators may discontinue development in the future. If that were to occur, we may have to curtail the development of a particular product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our 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 will not be able to bring our product candidates to market and generate product revenue. In instances where we have or do enter into collaborations, we could be subject to the following risks, each of which may materially harm our business, commercialization prospects, and financial condition: we may not be able to control the amount and timing of resources that is required of us to complete our development obligations or that the collaboration partner devotes to the product development or marketing programs; the~~

collaboration partner may experience financial difficulties; 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; we may be required to relinquish important rights such as marketing, distribution, and intellectual property rights; collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors; we and our collaboration partner may disagree regarding the development plan for research and development projects or product candidates on which we are collaborating (for example, we may disagree with a collaboration partner regarding target indications or inclusion or exclusion criteria for a clinical trial); or business combinations or significant changes in a collaborator's business strategy may adversely affect our willingness to complete our obligations under any arrangement. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue, or specific net income that justifies such transaction.

Risks Related to Intellectual Property

Property We depend on intellectual property licensed or acquired from third parties and we are currently party to in - license agreements under which we acquired rights to use, develop, manufacture and / or commercialize certain of our proprietary technologies and product candidates. If we breach our obligations under these agreements or if any of these agreements is terminated, or otherwise experience disruptions to our business relationships with our licensors, we may be required to pay damages, **and / or** lose our rights to such intellectual property and technology, **or both**, which would harm our business. We are dependent on patents, know - how, and proprietary technology, both our own and licensed from others. We are a party to intellectual property license agreements and in the future, we may enter into additional license agreements. For example, with respect to developing our product candidates, we have licensed or acquired, as the case may be, certain intellectual property from Amgen, Blackthorn, TSRI and Vanderbilt. These license and acquisition agreements impose, and we expect that future license and acquisition agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, we may be required to pay damages and the licensor may have the right to terminate the license. Any termination of these licenses could result in the loss of significant rights and could harm our ability to develop, manufacture and / or commercialize our product candidates. See the section titled " Business — Intellectual Property — In - Licensing and Collaboration Agreements " in **this the** Annual Report on Form 10- K for additional information regarding these key agreements. In addition, the agreements under which we license or acquire intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed or acquired prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability. If we are unable to successfully obtain rights to required third - party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant research programs or product candidates and our business, financial condition, results of operations and prospects could suffer. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may also arise between us and our current and future licensors regarding intellectual property subject to a license or collaboration agreement, including those relating to:

- the scope of rights granted under the license or collaboration agreement and other interpretation - related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of patented technology;
- rights upon termination of the license agreements;
- the scope and duration of exclusivity obligations of each party to the license agreements;
- the amount and timing of payments owed under license agreements; and
- the allocation of ownership of inventions and know - how resulting from the joint creation or use of intellectual property by our licensors or collaborators and by us and our partners.

The resolution of any contractual interpretation dispute that may arise, if unfavorable to us, could have a material adverse effect on our business, financial condition, results of operations and prospects. Such resolution could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement or decrease the third party's financial or other obligations under the relevant agreement. Furthermore, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected

product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer. We depend, in part, on our licensors to file, prosecute, maintain, defend, and enforce certain patents and patent applications that are material to our business. Certain patents and patent applications relating to our product candidates are owned or controlled by certain of our licensors. In some circumstances, we may not have the right to control the preparation, filing, prosecution, maintenance, and defense of patent applications or patents covering technology that we license from third parties. In such circumstances, our licensors generally have rights to file, prosecute, maintain, and defend the licensed patents in their name, generally with our right to comment on such filing, prosecution, maintenance, and defense, with some obligation for the licensor to consider or incorporate our comments. We generally have the first right to enforce our exclusively licensed patent rights against third parties, although our ability to settle such claims often requires the consent of the licensor. If our licensors or any future licensees having rights to file, prosecute, maintain, and defend our patent rights fail to conduct these activities for patents or patent applications covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, or selling competing products. We cannot be certain that such activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even in the circumstances where we have the right to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control. This could cause us to lose rights in any applicable intellectual property that we in - license, and as a result our ability to develop and commercialize product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products. Given the breadth of the application of our precision neuroscience approach, in order to increase our ability to exploit our technologies, we may enter into collaborations and / or strategic partnerships in the future, and we may not realize the anticipated benefits of such collaborations or partnerships. We may not be able to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans. Research and development collaborations and strategic partnerships are prevalent in the biopharmaceutical industry. The breadth of the application of our precision neuroscience approach is an attractive technology for potential collaborations and / or strategic partnerships. **These transactions** **Our existing and any future collaborations or strategic partnerships** are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration, and may not commit sufficient efforts and resources, or may misapply those efforts and resources;
- collaborators may not pursue development and commercialization of collaboration product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results or changes in their strategic focus;
- collaborators may delay, provide insufficient resources to, or modify or stop clinical trials for collaboration product candidates;
- collaborators could develop or acquire products outside of the collaboration that compete directly or indirectly with our products or product candidates;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause 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 and personnel to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co - own intellectual property covering our products that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property.

The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We may form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop, including in territories outside the United States or for certain indications. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write - downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or in - license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction

or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time - consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our 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 our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. Our ability to reach a definitive agreement for a collaboration will depend, 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 our technologies, product candidates and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators. As a result of these risks, we may not be able to realize the benefit of our existing collaboration or any future collaborations or licensing agreements we may enter into. 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 and changes to the strategies of the combined company. As a result, 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 such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing 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. Our product candidates may also require specific components to work effectively and efficiently, and rights to those components may be held by others. We may be unable to in - license any compositions, methods of use, processes or other third - party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. In that event, we may be required to expend significant time and resources to develop or license replacement technology. 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. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies, which could harm our business prospects, financial condition and results of operations. Moreover, some of our owned and in - licensed patents or patent applications or future patents are or may be co - owned with third parties. If we are unable to obtain an exclusive license to any such third - party co - owners' interest in such patents or patent applications, such co - owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co - owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, our owned and in - licensed patents may be subject to a reservation of rights by one or more third parties. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. We may not be successful in obtaining or maintaining necessary rights for our product pipeline which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated. We own or license from third parties certain intellectual property rights necessary to develop our product candidates. The growth of our business will likely depend in part on our ability to acquire or in - license additional proprietary rights, including to expand our product pipeline. In that event, we may be required to expend considerable time and resources to develop or license replacement technology. For example, our programs may involve additional technologies or product candidates that may require the use of additional proprietary rights held by third parties. Furthermore, other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. Our product candidates may also require specific formulations or other technology to work effectively and efficiently. These formulations or technology may be covered by intellectual property rights held by others. From time to time, in order to avoid infringing these third - party rights, we may be required to license technology from additional third parties to further develop or commercialize our product candidates. We may be unable to acquire or in - license any relevant third - party intellectual property rights, including any such intellectual property rights required to manufacture, use or sell our product candidates, that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, and as a result we may be unable to develop or commercialize the affected product candidates, which would harm our business. We may need to cease use of the compositions or methods covered by such third - party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non - exclusive, which may allow our competitors' access to the same technologies licensed to us. Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program. If we are unable to

successfully obtain rights to required third - party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer. The licensing and acquisition of third - party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third - party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. We may be dependent on intellectual property licensed or sublicensed to us from, or for which development was funded or otherwise assisted by, the U. S. government and / or government agencies, such as the National Institutes of Health, for development of our technology and product candidates. Failure to meet our own obligations to our licensors or upstream licensors, including such government agencies, may result in the loss of our rights to such intellectual property, which could harm our business. The U. S. government and / or government agencies have provided, and in the future may provide, funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. The U. S. government and / or government agencies may have retained rights in such intellectual property, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses, could result in the loss of significant rights and could harm our ability to commercialize licensed products. For example, the research resulting in certain of our in - licensed patent rights and technology was funded in part by the U. S. government. As a result, the government may have certain rights, or march - in rights, to such patent rights and technology. These rights may permit the government to disclose our confidential information to third parties and to exercise march - in rights to use or allow third parties to use our licensed technology. If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and approach, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected. We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and / or unenforceable. We or our licensors have filed **patent applications**, and we anticipate that in the future we will file additional patent applications both in the United States and in other countries, as appropriate. However, we cannot predict: • if and when any patents will issue; • the degree and range of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents; • whether others will apply for or obtain patents claiming aspects similar to those covered by our patents and patent applications; • whether we will need to initiate litigation or administrative proceedings to defend our patent rights, which may be costly whether we win or lose; or • whether the patent applications that we own or in - license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and approach. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Obtaining and enforcing patents is expensive and time - consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and / or enforce patents that may issue based on our 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 results before it is too late to obtain patent protection. Although we enter into non - disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, **CROs contract research organizations**, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Our ability to enforce patent rights also depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor' s or potential competitor' s product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. If we initiate lawsuits to protect or enforce our patents, or litigate against third - party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel. Composition of matter patents for biopharmaceutical products often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain, however, that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO), or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “ off - label ” for those uses that are covered by our method of use patents. Although off - label prescriptions may infringe or contribute to the infringement of

method of use patents, the practice is common and such infringement can be difficult to prevent or prosecute. The strength of patents in the biotechnology, biopharmaceutical and data science fields can be uncertain, and evaluating the scope of such patents involves complex legal, factual and scientific analyses and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. The patent applications that we own or in - license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, this could dissuade companies from collaborating with us to develop, and could threaten our ability to commercialize, our product candidates. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. We may not identify relevant third - party patents or may incorrectly interpret the relevance, scope or expiration of a third - party patent, which might adversely affect our ability to develop and market our products. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third - party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third - party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Further, we may not be aware of all third - party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third - party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third - party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are confidential for typically a period of 18 months after filing, or may not be published at all, we cannot be certain that we were the first to file any patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, for U. S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U. S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the America Invents Act, which brought into effect significant changes to the U. S. patent laws, including new procedures for challenging pending patent applications and issued patents. Our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third - party pre - issuance submission of prior art to the USPTO or become involved in post - grant review procedures, oppositions, derivations, reexaminations, or inter partes review proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary

technologies that are patentable; • we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in - license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; • the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties; • if enforced, a court may not hold that our patents are valid, enforceable and infringed; • we may need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose; • we may choose not to file a patent in order to maintain certain trade secrets or know - how, and a third party may subsequently file a patent covering such intellectual property; • we may fail to adequately protect and police our trademarks and trade secrets; and • the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications. Should any of these events occur, they could significantly harm our business, results of operations and prospects. Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know - how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our product candidates, technology and product discovery and development processes that involve proprietary know - how, information, or technology that is not covered by patents. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third - party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Trade secrets and confidential information, however, may be difficult to protect. We seek to protect our trade secrets, know - how and confidential information, including our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. 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 and processes. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time - consuming, and the outcome is unpredictable. 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 from using that technology or information to compete with us. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, **operating results of operations**, and financial condition. Third - party claims of intellectual property infringement against us or our collaborators may prevent or delay our product discovery and development efforts. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post - grant review and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Furthermore, patent reform and changes to patent laws add uncertainty to the possibility of challenge to our patents in the future. We cannot assure you that our product candidates and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Numerous U. S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. We cannot provide any assurances that third - party patents do not exist which might be enforced against our current product candidates or future products, resulting in either an injunction prohibiting our sales, or, with

respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Third parties may assert that we infringe their patents or other intellectual property, or that we are otherwise employing their proprietary technology without authorization, and may sue us. There may be third - party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture, or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates and other proprietary technologies we may develop, could be found to be infringed by our product candidate. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties, our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may obtain patents in the future that may prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates, and may claim that use of our technologies or the manufacture, use, or sale of our product candidates infringes upon these patents. If any such third - party patents were held by a court of competent jurisdiction to cover our technologies or product candidates, or if we are found to otherwise infringe a third party' s intellectual property rights, the holders of any such patents may be able to block, including by court order, our ability to develop, manufacture or commercialize the applicable product candidate unless we obtain a license under the applicable patents or other intellectual property, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non - exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to obtain a necessary license to a third - party patent on commercially reasonable terms, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. The biopharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U. S. patent. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. Third parties asserting their patent or other intellectual property rights against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates or force us to cease some of our business operations. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, cause development delays, and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties, or redesign our infringing products, which may be impossible on a cost - effective basis or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. We may not be able to protect our intellectual property rights throughout the world. Patents are of national or regional effect, and filing, prosecuting, maintaining and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can have a different scope and strength than do those in the United States. In addition, the laws of some foreign countries, particularly certain developing countries, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or adequate 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, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation 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. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be

without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. In addition, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's conflict in Ukraine, the ongoing conflict between Israel and Hamas, and other matters may limit or prevent filing, prosecution, and maintenance of patent applications in Russia, Israel and other countries. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia, Israel and other countries. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Finally, Europe's ~~planned~~ Unified Patent Court (~~or the UPC~~) may, in particular, present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. In 2012, the European Patent Package (~~or the EU Patent Package~~) regulations were passed with the goal of providing a single pan-European Unitary Patent system and ~~UPC~~ a new European Unified Patent Court for litigation involving European patents. The Unitary Patent system and ~~UPC~~ ~~successfully~~ launched on June 1, 2023. Under the UPC, all European patents, including those issued prior to ratification of the ~~European EU~~ Patent Package, now by default automatically fall under the jurisdiction of the UPC. The UPC provides our competitors with a new forum to centrally revoke our European patents, and allows for the possibility of a competitor to obtain pan-European injunctions. Such a loss of patent protection could have a material adverse impact on our ~~business and our~~ ability to commercialize our technology and product candidates and ~~resultantly~~, on our business, financial condition, prospects and results of operations. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the current EU Patent Package, we have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patents, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action, which typically last for years before they are concluded, may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings and that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market. We may be involved in lawsuits to protect or enforce our patents or other intellectual property or the intellectual property of our licensors, which could be expensive, time-consuming, and unsuccessful. Competitors may infringe our patents or other intellectual property or the intellectual property of our licensors. To cease such infringement or unauthorized use, we may be required to file patent infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. In addition, in an infringement proceeding or a declaratory judgment action, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and 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 harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation, interference, derivation or other proceedings may result in a decision

adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign authority. If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim we infringe their patents or that the patent covering our product candidate is invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent, including lack of novelty, obviousness, non-enablement or insufficient written description or that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post-grant review, and equivalent proceedings in foreign jurisdictions, such as opposition or derivation proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U. S. C. § 271I (1). With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates and such an outcome may limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Such a loss of patent protection could have a material adverse impact on our business. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. **Recent patent Patent** reform legislation in the United States and other countries, including the Leahy - Smith America Invents Act, or the Leahy - Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy - Smith Act includes **a number of significant changes to U. S. patent law. These include** provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. After March 2013, under the Leahy - Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant **going forward** of the time from invention to filing of a patent application. **Since Because** patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (1) file any patent application related to our product candidates and other proprietary technologies we may develop or (2) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy - Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created

uncertainty with respect to the value of patents once obtained. Depending on decisions by Congress, the federal courts, the USPTO and the relevant law - making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. ~~We For example, in a series of cases, the U. S. Supreme Court held that certain claims do not present patentable subject matter (Mayo Collaborative Services v. Prometheus Laboratories, Inc. (2012); Assoc. for Molecular Pathology v. Myriad Genetics, Inc. (2013); Alice Corp. v. CLS Bank International (2014)). Although we do not believe that any of the patents owned or licensed by us will be found invalid based on these decisions, we~~ cannot predict how future decisions by Congress, the federal courts or the USPTO may impact the value of our patents. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non - compliance with these requirements. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse on us or our patent maintenance vendors, can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non - payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business. The lives of our patents may not be sufficient to effectively protect our products and business. Patents have a limited lifespan. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. 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 product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic medications. The launch of a generic version of one of our products in particular would be likely to result in an immediate and substantial reduction in the demand for that product, which could have a material adverse effect on our business, financial condition, results of operations and prospects. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. In addition, although upon issuance in the United States a patent' s life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co - inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co - ownership of potential joint inventions. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. We or our licensors may have relied on third - party consultants or collaborators or on funds from third parties, such as the U. S. government, such that we or our licensors are not the sole and exclusive owners of the patents we in - licensed. If other third parties have ownership rights or other rights to our patents, including in - licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may

be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. If our trademarks and trade names are not adequately protected, ~~then~~ we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive, or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks.

Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to 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. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Risks Related to Ownership of Our Common Stock

Our stock price has experienced volatility and declines and may continue to be volatile or may decline, regardless of our operating performance, resulting in substantial losses for investors. The market price of our common stock **has been and may continue to be highly volatile and may fluctuate further decline** substantially as a result of a variety of factors, some of which are related in complex ways. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including the factors listed below and other factors described in this “Risk Factors” section of this Annual Report on Form 10-K: **the commencement of, enrollment in, or results of current and future preclinical studies and clinical trials we may conduct, or changes in the development status of our product candidates; adverse results or delays in clinical trials; unanticipated serious safety concerns related to the use of our product candidates; any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority’s review of such filings, including, without limitation, the issuance by the FDA of a “refusal to file” letter or a request for additional information; changes in laws or regulations, including, but not limited to, preclinical study or clinical trial requirements for approvals; negative clinical outcomes or other adverse events related to product candidates being developed by others in the CNS field; publication of research reports about us or our industry, or CNS programs in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts; any adverse changes to our relationship with manufacturers or suppliers; manufacturing, supply or distribution shortages; our failure to commercialize our product candidates; general political conditions, including but not limited to, disruptions in U. S. government operations and funding, geopolitical conflicts such as the war between Russia and the Ukraine, the war between Israel and Hamas, and any sanctions or other repercussions that may result therefrom; general economic conditions, including but not limited to, rising inflation, tariffs, recession risk, low consumer confidence and increasing interest rates; additions or departures of key scientific or management personnel; disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies; variations in our results of operations; our cash position; our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; announcements made by us or our competitors of new product and service offerings, acquisitions, strategic relationships, joint ventures, or capital commitments; our inability to establish collaborations, if needed; our ability to effectively manage our growth; changes in the market valuations of similar companies; press reports, whether or not true, about our business; sales or perceived potential sales of our common stock by us or our stockholders in the future; overall fluctuations in the equity markets; ineffectiveness of our internal controls; changes or developments in the global regulatory environment; litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors; impact from the COVID - 19 pandemic, or any future pandemic, on us or third parties with which we engage; and other events or factors, many of which are beyond our control. In addition, the stock market in general and biotechnology and**

biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating **performance**, which may limit or prevent investors from selling their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock. Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. We expect our operating results to be subject to quarterly fluctuations, which will make it difficult for us to predict our future results. Our net loss and other operating results will be affected by numerous factors, including: • timing and variations in the level of expense related to the current or future development of our programs, including but not limited to, the timing of the milestone payments; • our ability to enroll patients in clinical trials and timing and status of enrollment for our clinical trials; • results of clinical trials, or the addition or termination of, **or changes to** clinical trials or funding support by us or potential future partners; • the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated; • competition from products that compete with our product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners; • any delays in regulatory review or approval of our product candidates; • stock - based compensation estimates; • changes in general political conditions, including but not limited to, disruptions in U. S. government operations and funding, geopolitical conflicts such as the war between Russia and the Ukraine, the war between Israel and Hamas, and any sanctions or other repercussions that may result therefrom; • changes in general economic conditions, including but not limited to, **rising** inflation, **tariffs**, recession risk, low consumer confidence and **increasing** interest rates; • our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements; • any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved; • additions and departures of key personnel; • strategic decisions by us or our competitors, such as acquisitions, divestitures, spin - offs, joint ventures, strategic investments or changes in business strategy; • if any product candidate we may develop receive regulatory approval, the timing and terms of such approval and market acceptance and demand for such product candidates; • the timing and cost to establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with current or future collaborators; • 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 any of our product candidates; • our ability to commercialize our product candidates, if approved, inside and outside of the United States, 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; • regulatory developments affecting current or future product candidates or those of our competitors; and • impact from the COVID - 19 pandemic, or any future pandemic, on us or third parties with which we engage. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. As of December 31, **2023-2024**, our executive officers, directors, holders of 5 % or more of our capital stock and their respective affiliates owned approximately **48 55-67%** of our outstanding voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. In addition, certain of our principal stockholders, including Amgen, ARCH Venture Partners and Mubadala Capital, have designated certain of our directors for election to ~~the our Board~~ **board of directors**. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. Sales of a substantial number of shares of our common stock in the public market could cause our common stock price to fall. If our existing stockholders sell, or indicate an intention to sell, or if the market perceives that such existing stockholders might sell, substantial amounts of our common stock in the public market ~~after the lock-up and other legal restrictions on resale lapse~~, the market price of our common stock could decline. As of **December 31, 2024** ~~the completion of our initial public offering (including the partial exercise by the underwriters of their option to purchase additional shares)~~, we had outstanding a total of **152-161 , 832-709 , 352-907** shares of common stock . ~~Of these~~ **and approximately 48 % of such** shares **were beneficially owned by our directors**, substantially all **officers, and holders of the shares-5 % or more** of our common stock ~~sold in the initial public offering are freely tradable, without restriction, in the public market. The lock-up agreements entered into in connection with our IPO will expire at the close of business on March 12, 2024. J. P. Morgan Securities LLC and BofA Securities, Inc., in their sole discretion, may permit our equity holders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, the shares of common stock will be eligible for sale in the public market. Approximately 55. 65 % of these additional shares are owned by directors, executive officers and other affiliates and will be subject to certain limitations of Rule 144 under the Securities Act of 1933, as amended (the "Securities Act").~~ In addition, approximately **37-38 , 902-591 , 417-940** shares of common stock that are either subject to outstanding options or reserved for future issuance under our **equity incentive employee benefit** plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules , ~~the lock-up agreements~~ and Rule 144 and Rule 701 under the Securities Act **of 1933, as amended (Securities Act)**. If these additional shares of common stock are sold, or **there** if it is **perceived a perception** that they will be sold, in the public

market, the market trading price of our common stock could decline. Further, in addition, the certain holders of approximately 123.8 million shares, of or our 86% of our total outstanding common, have stock are entitled to rights, subject with respect to the some conditions, to require us to file registration statements covering the sale of their shares under or to include their -- the Securities Act shares in registration statements that we may file for ourselves or our other stockholders, subject to the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the market trading price of our common stock. In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. For example, in October 2024 we entered into a sales agreement with Leerink to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to \$ 300. 0 million, through an ATM program with Leerink as the sales agent. During the year ended December 31, 2024, we received aggregate net proceeds of \$ 13. 7 million through sales of shares of our common stock under the ATM, after deducting commissions and offering expenses of \$ 0. 8 million. In December 2023, we settled a Phase 3 navacaprant milestone owed to Blackthorn stockholders by primarily issuing shares of our common stock. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline. We do not currently intend to pay dividends on our common stock and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation of the value of our common stock. We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value for our common stock, which is not certain. Provisions in our amended and restated certificate of incorporation and our amended and restated 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 common stock. Our amended and restated certificate of incorporation 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: • establish a staggered board of directors divided into three classes serving staggered three - year terms, such that not all members of the board of directors will be elected at one time; • authorize our board of directors to issue new series of preferred stock without stockholder approval and create, subject to applicable law, a series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock; • eliminate the ability of our stockholders to call special meetings of stockholders; • eliminate the ability of our stockholders to fill vacancies on our board of directors; • establish advance notice requirements for nominations for election to our Board board of directors or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings; • permit our board of directors to establish the number of directors; • provide that our board of directors is expressly authorized to make, alter or repeal our amended and restated bylaws; • provide that stockholders can remove directors only for cause and only upon the approval of not less than 66 - 2 / 3 % of all outstanding shares of our voting stock; • require the approval of not less than 66 - 2 / 3 % of all outstanding shares of our voting stock to amend our amended and restated bylaws and specific provisions of our certificate of incorporation; and • limit the jurisdictions forums in which certain stockholder litigation may be brought. As a Delaware corporation, we are subject to the anti - takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in a business combination specified in the statute with an interested stockholder (as defined in the statute) for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in advance by a majority of the independent directors or by the holders of at least two - thirds of the outstanding disinterested shares. The application of Section 203 of the Delaware General Corporation Law could also have the effect of delaying or preventing a change of control of our company. Our amended and restated certificate of incorporation provides an exclusive forum in the Court of Chancery of the State of Delaware for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (3) any action asserting a claim against us or any director, officer, or other employee arising pursuant to the Delaware General Corporation Law, (4) any action to interpret, apply, enforce, or determine the validity of our second amended and restated certificate of incorporation or amended and restated bylaws or (5) any other action asserting a claim that is governed by the internal affairs doctrine, is the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court' s having jurisdiction over indispensable parties named as defendants. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the forum selection provision does apply to claims brought to enforce a duty or liability created by the Exchange Act. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may result in increased costs to stockholders to bring a claim for any such dispute and may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such

action in other jurisdictions, which could harm our business, financial condition, and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock will be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Our ability to use our net operating loss carryforwards and other tax attributes may be limited. 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 greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three - year period, the corporation’s ability to use its pre - change net operating loss carryforwards (NOLs) and other pre - change tax attributes (such as research and development tax credits) to offset its post - change income or taxes may be limited. We may have experienced ownership changes in the past and may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which are outside our control). As a result, our ability to use our pre - change NOLs and tax credits to offset future taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

General Risk Factors ~~Factors~~ ~~If~~ securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the trading price or trading volume of our common stock could decline. The trading market for our common stock is influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market, or our competitors. If one or more of these analysts initiate research with an unfavorable rating or downgrade our common stock, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If any analyst covering us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. ~~As widely reported, global~~ **Global** credit and financial markets have experienced extreme volatility and disruptions ~~over the past several months, due to a number of factors~~ including concerns about declines in consumer confidence, declines in economic growth, ~~increases in the rate of~~ inflation, ~~increases in~~ **tariffs**, borrowing rates and changes in liquidity and credit availability, and uncertainty about economic stability, including ~~most recently~~ in connection with actions undertaken by the U. S. Federal Reserve Board to address inflation, the failure of banks, the military conflict in Ukraine, the war between Israel and Hamas ~~, the continuing effects of the COVID - 19 pandemic~~ and supply chain disruptions. There can be no assurance that future deterioration in global credit and financial markets and confidence in economic conditions 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, it may make any necessary debt or equity financing more difficult, more costly and more dilutive, if at all possible. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and 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 an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget. An active trading market for our common stock may not develop or be sustained. Prior to our initial public offering in September 2023, there was no public market for shares of our common stock. ~~Our common stock is currently listed on the Nasdaq Global Select Market under the symbol “NMRA”.~~ The price for our common stock may vary and an active or liquid market in our common stock may not be sustained. The lack of an active market may impair the value of your shares, your ability to sell your shares at the time you wish to sell them and the prices that you may obtain for your shares. An inactive market may also impair our ability to raise capital by selling our common stock and our ability to acquire other companies, products or technologies by using our common stock as consideration. ~~The continuing impact of “Brexit” may have a negative effect on our business. Following a national referendum and subsequent legislation, the United Kingdom formally withdrew from the European Union, commonly referred to as “Brexit,” and ratified a trade and cooperation agreement governing its future relationship with the European Union. Among other things, the agreement, which became effective in 2021, addresses trade, economic arrangements, law enforcement, judicial cooperation and governance. While the agreement provides a framework for cooperation between the UK and the EU including for example the mutual recognition of Good Manufacturing Practice (GMP) inspections of manufacturing facilities for medicinal products, it does not contain wholesale mutual recognition of pharmaceutical regulations and product standards. There may therefore be divergent local requirements in the UK compared to the EU in the future, which may increase the costs of conducting clinical and development activities in the UK. We were~~ cannot yet predict the full implications of Brexit, including whether it will increase our operational costs or otherwise have a negative effect on our business, financial condition or results of operations, which could reduce the price of our common stock. We are ~~an emerging growth company and a smaller reporting company~~ **until December 31, 2024**, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock less attractive to investors. **The loss of emerging growth company and smaller reporting company status and compliance with additional disclosure requirements will increase our legal and financial compliance costs.** We are ~~were~~ an “emerging growth company” as defined in the JOBS Act and a “smaller reporting company,” as defined in the Exchange Act **until December 31, 2024**. **Accordingly** ~~For as long as we continue to be an emerging growth company,~~ we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies **or smaller reporting companies in this Annual Report on Form 10- K (including those sections incorporated**

by referenced to our Proxy Statement for our 2025 Annual Meeting of Stockholders)), including: ~~• not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;~~ reduced disclosure obligations regarding executive compensation in our periodic reports and annual report on Form 10-K; and ~~• exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the completion of our initial public offering. Our status as an emerging growth company will end as soon as any of the following takes place: the last day of the fiscal year in which we have more than \$1.235 billion in annual revenue; the date we qualify as a “large accelerated filer,” with at least \$700.0 million of equity securities held by non-affiliates; the date on which we have issued, in any three-year period, more than \$1.0 billion in non-convertible debt securities; or the last day of the fiscal year ending after the fifth anniversary of the completion of our initial public offering. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for any new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. Even after we no longer qualify as an emerging growth company, we may continue to qualify as a smaller reporting company, which would allow us to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. We are also exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404(b) of the Sarbanes-Oxley Act. These exemptions and reduced disclosures due to our status as a smaller reporting company mean that our auditors do not review our internal controls over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded to emerging growth companies and smaller reporting companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.~~ The requirements of being a public company may strain our resources, result in more litigation, and divert management’s attention. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act ~~(, or the Dodd-Frank Act,)~~ the listing requirements of Nasdaq, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management’s attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses. In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time consuming. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations, and standards differ from the activities intended by regulatory or governing bodies ~~due to ambiguities related to their application and practice~~, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected. These ~~new~~ rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers. By disclosing information in filings required by us as a public company, our business and financial condition will continue to become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management’s resources and seriously harm our business.

Emerging growth companies are permitted to implement many of these requirements over time, however we are no longer an emerging growth company as of December 31, 2024 and expect to incur additional compliance-related expenses as a result. Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. The occurrence of

any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired. Pursuant to Section 404 of the Sarbanes - Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting ~~when we lose our status as an~~ **and beginning with this Annual Report on Form 10-K, we** ~~“emerging growth company” and become an “accelerated filer” or a “large -- are accelerated filer.”~~ At that point, we will be required to have an independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex, judgmental and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if we and / or our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our consolidated financial statements, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. 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 must design 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 realities that judgments in decision - making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. 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. If our estimates or judgments relating to our critical accounting policies prove to be incorrect or financial reporting standards or interpretations change, our results of operations could be adversely affected. The preparation of financial statements in conformity with generally accepted accounting principles in the United States (U. S. GAAP), requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, as provided in “Management’ s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates. ” The results of these estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Significant assumptions and estimates used in preparing our consolidated financial statements include but are not limited to stock - based compensation and evaluation of acquisitions of assets and other similar transactions as well as clinical trial accruals. Our results of operations may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our results of operations to fall below the expectations of securities analysts and investors, resulting in a decline in the trading price of our common stock. Additionally, we regularly monitor our compliance with applicable financial reporting standards and review new pronouncements and drafts thereof that are relevant to us. As a result of new standards, changes to existing standards and changes in their interpretation, we might be required to change our accounting policies, alter our operational policies, and implement new or enhance existing systems so that they reflect new or amended financial reporting standards, or we may be required to restate our audited consolidated financial statements, unaudited condensed consolidated financial statements and related notes. Such changes to existing standards or changes in their interpretation may also have an adverse effect on our reputation, business, financial ~~position - condition~~ , and ~~profit - results of operations~~ . Our information technology systems, or those used by our third - party research institution collaborators, CROs, ~~CDMOs - CMOs~~ , or other contractors or consultants, may fail or suffer cyberattacks or security breaches. We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information , **clinical trial data**, and personal information of our ~~customers, employees , and contractors~~). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third - party contractors who have access to our confidential information. Despite the implementation of security measures, our information technology systems and those of our ~~future CROs and , CDMOs - CMOs~~ , and other contractors and consultants are vulnerable to attack, damage, or interruption from hacking, cyberattacks, “ phishing ” attacks and other social engineering schemes, computer viruses and malware (e. g., ransomware), malicious code, denial or degradation of service attacks, sophisticated nation - state and nation - state supported actors, unauthorized access or use by persons within our organization, natural disasters, terrorism, war and telecommunication and electrical failures, employee theft or misuse, human error, and fraud. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted

by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the continued hybrid working environment, we ~~may~~ also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. We and certain of our service providers are from time to time subject to cyberattacks and security incidents, including social engineering and phishing attacks. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Although to our knowledge we have not experienced any such material system failure, accident, or security breach to date, if such an event were to occur and negatively affect our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Further, we cannot ~~assure~~ **ensure** that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. Likewise, we rely on our third - party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their information technology systems could also have a material adverse effect on our business. To the extent that any disruption or security incident were to result in an actual or perceived loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information or patient information, we could incur liability and the further development and commercialization of our product candidates could be delayed. 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, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information 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 mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. We have **entered** and **will expect to** enter into collaboration, license, contract research and / or manufacturing relationships with organizations that operate in certain countries that are at heightened risk of theft of technology, data and intellectual property through direct intrusion by private parties or foreign actors, including those affiliated with or controlled by state actors. Accordingly, our efforts to protect and enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, and we may be at heightened risk of losing our proprietary intellectual property rights around the world, including outside of such countries, to the extent such theft or intrusion destroy the proprietary nature of our intellectual property. We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties. We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or biopharmaceutical companies. Although we try to ensure that individuals working for or collaborating with us do not use the proprietary information or know - how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information proprietary to these third parties or our employees' former employers, or that we caused an employee to breach the terms of his or her non - competition or non - solicitation agreement. We may be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants, advisors or other third parties, **even including** those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. We ~~could be~~ **are currently** subject to **and may be subject to additional future** securities class action litigation. ~~In the past, securities~~ **Securities** class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. **For example, on February 6, 2025, a purported stockholder of the Company filed a lawsuit against us, certain of our executive officers, and certain underwriters in the United States District Court for the Southern District of New York alleging violations of the Securities Act related to our initial public offering. See the section titled " Legal Proceedings " in this Annual Report on Form 10- K for additional information regarding this matter.** ~~This type of~~ litigation, ~~if instituted,~~ could result in substantial costs and a diversion of management' s attention and resources, which would

harm our business, ~~operating~~ results **of operations**, or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiff.