Risk Factors Comparison 2025-03-24 to 2024-03-13 Form: 10-K

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Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with the other information in this Annual Report, including our consolidated financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " before deciding whether to invest in our securities. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have a material adverse effect on our business, reputation, revenue, financial condition, results of operations, and future prospects, in which event the market price of our Common Stock could decline, and you could lose part or all of your investment. The risks and uncertainties summarized above and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Annual Report also contains forward- looking statements that involve risks and uncertainties, refer to " Cautionary Note Regarding Forward- Looking Statements. " Our actual results could differ materially and adversely from our anticipated results as a result of a number of factors, including the risks described below. Risks Relating to Our Business and Industry We depend substantially on the successful commercialization of our drug candidates in the future, which may fail to materialize or may experience significant delays. **We** ~~As a new biopharmaceutical business, we~~ currently do not have any drugs available for commercial sales nor do we have any drugs that have been approved for sale by the regulatory authorities. We have invested a significant portion of our efforts and financial resources in research and development of our leading drug candidate, CNM- Au8, a catalytically- active gold nanocrystal suspension, which in early- stage studies has shown potential for the treatment of patients with ALS, MS, and PD. Our ability to generate revenue and become profitable in the future depends substantially on the future sales generated by CNM- Au8 and our drug candidates, which in turn depends on the successful research and development, regulatory approval, commercialization and sale of our drug candidates presently under clinical development for the treatment of patients with neurological disorders. We are also developing new drugs based on our technology that have not yet entered into human studies. The ultimate success of our drug candidates is subject to us achieving certain milestones, including without limitation: ● identifying, assessing, acquiring and obtaining evidence of biological activity of new drug candidates to treat certain diseases; ● obtaining satisfactory evidence of safety of these drug candidates in animal toxicology studies; ● obtaining regulatory approval for the conduct of, enrollment in, and completion of, clinical trials of our drug candidates; ● obtaining satisfactory proof of the clinical efficacy and safety of our drug candidates from these clinical trials; ● obtaining approvals and marketing authorizations from regulatory authorities for our drug candidates; ● developing sustainable and scalable manufacturing processes to produce these drug candidates; ● successfully expanding manufacturing processes to support global commercialization capacity of our drug candidates; and ● launching and commercializing any drug candidates for which we may obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor. If we do not achieve one or more of these milestones in a timely manner, or at all, we could experience significant delays in our ability to obtain approval for and / or to successfully commercialize our drug candidates, which could materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations. Even if we are able to generate revenues from any future sales of our drug candidates, we may not become profitable and may need to obtain additional funding to continue operations. Any required funding may not be available on favorable terms or at all. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease our value significantly and could impair our ability to raise capital, expand our business or continue our operations, which in turn may adversely affect our business, financial condition, and results of operations. We currently do not generate any revenue from the commercial sales of drug candidates and we may not become profitable when expected, or at all. Our main business is research and development, and if successful, sales of drug candidates. As all of our drug candidates are still in the research and development stage, we currently do not generate revenue from the sale of drug candidates, and we have recorded continued significant net losses. We generate an immaterial amount of revenue related to license and supply agreements for dietary (mineral) supplements; however, such revenue is not expected to be a material contributor to our revenue in the future. If we fail to commercialize our drug candidates as planned due to failures to complete clinical trials, obtain regulatory approval, conduct commercial scale manufacturing or for any other reason, we may experience significant delays or failure in generating revenue and realizing profit from the commercial sale of our drug candidates. Further, we expect to incur significant costs in the future, in particular for research and development and the commercialization of our drug candidates. Research and development expenses totaled $ **20. 1 million and $** 26. 7 ~~million and $ 31. 9~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~, respectively. As drug candidates presently undergoing preclinical research enter into the clinical trial stage, costs associated with such drug candidates may increase significantly. In the future, as we move more drug candidates into the clinical trial stage, conduct more clinical trials for commercialized products, if any, to broaden their use, and carry out commercial production of our drug candidates, the costs associated with such operations may increase significantly. As we operate in the highly competitive pharmaceutical market, we compete to commercialize our drug candidates ahead of our competitors, putting us under pressure to incur research and development and other expenses with a potential negative impact on our profitability. On the other hand, our commercialized drug candidates, if any are approved, may fail to realize their sales potential due to competition, insufficient market demand,

product defects, or any other reason. Therefore, even if we ever start to generate revenue from the sales of our commercialized drug candidates in the future, we may still not be profitable for an extended period of time or at all. We have incurred significant net losses and net operating cash outflows since our inception and expect to continue to incur significant net losses for the foreseeable future. Investment in biopharmaceutical drug development is highly speculative. It entails substantial upfront capital expenditures and significant risk that a drug candidate might fail to gain regulatory approval or become commercially viable. We continue to incur significant expenses related to our ongoing operations. We have incurred substantial losses since our inception. We incurred a loss from operations of $ **33. 1 million and $** 40. 5 ~~million and $ 48. 4~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~, respectively, and a net loss of $ **39. 4 million and $** 49. 5 ~~million and $ 29. 9~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~, respectively. Our accumulated deficit was $ **282. 1 million and $** 242. 7 million ~~and $ 193. 2 million~~ as of December 31, **2024 and** 2023 ~~and 2022~~, respectively. For details, see " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and administrative expenses associated with our operations, and we expect that our research and development expenses will continue to increase in the future. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue to expand our development of, and seek regulatory approvals for, our drug candidates, and we continue to build up our commercialization capabilities. Typically, it takes many years to develop one new drug from the drug discovery stage to the time it is available for treating patients. In addition, we will continue to incur costs associated with operating as a public company and in support of our growth as a development- stage or commercial- stage pharmaceutical company. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of commercializing any approved products, our ability to generate revenues and the timing and amount of milestones and other payments we make or receive through arrangements with third parties. If any of our drug candidates fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Our failure to become and remain profitable would decrease our value significantly and impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our drug development or commercialization efforts. Our cash, cash equivalents, and marketable securities totaled $ **12. 2 million and $** 35. 0 million ~~and $ 23. 3 million~~ as of December 31, **2024 and** 2023 ~~and 2022~~, respectively, and net cash used in operating activities was $ **21. 3 million and $** 30. 2 ~~million and $ 39. 0~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~, respectively. We expect to continue to incur losses and use cash in operating activities for the foreseeable future. For details, please see " Management' s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources. " We expect that within the next twelve months, we will not have sufficient cash and other resources on hand to sustain our current operations or meet our obligations as they become due unless we obtain additional financing. Additionally, pursuant to our **senior secured convertible promissory notes (the " 2024 SSCP Notes "), we are required to maintain unrestricted cash and cash equivalents of at least $ 2. 0 million to avoid acceleration of the full balance of the 2024 SSCP Notes (see Note 8 to the consolidated financial statements). These conditions raise substantial doubt about the Company' s ability to continue as a going concern. To mitigate our funding needs, we plan to raise additional funding, including exploring equity financing and offerings, debt financing, licensing or collaboration arrangements with third parties, as well as utilizing our existing at- the- market facility and equity purchase agreement and potential proceeds from the exercise of outstanding warrants and stock options. These plans are subject to market conditions and reliance on third parties, and there is no assurance that effective implementation of our plans will result in the necessary funding to continue current operations. During the year ended December 31, 2024, we generated $ 2. 7 million of gross proceeds from our equity distribution agreement (the " ATM Agreement "), raised $ 3. 5 million from a registered direct offering of equity securities and an additional $ 3. 8 million from separate, concurrent private placements of equity securities, and raised $ 10. 0 million from the issuance of the 2024 SSCP Notes of which $ 7. 9 million was used to repay the remaining balance of our obligations under a** term loan with Avenue Venture Opportunities Fund, L. P. **Additionally** ~~(" Avenue ")~~, **subsequent** ~~we are required~~ to **December 31, 2024, we generated** ~~maintain unrestricted cash and cash equivalents of at least~~ $ **2.** 5 ~~. 0~~ million ~~to avoid acceleration~~ of **gross** ~~the full balance of the loan (see Note 8 to the consolidated financial statements). These conditions raise substantial doubt about the Company' s ability to continue as a going concern. To mitigate our funding needs, we plan to raise additional funding, including exploring equity financing and offerings, debt financing, licensing or collaboration arrangements with third parties, as well as utilizing our existing at- the- market facility, equity purchase agreement, and potential~~ proceeds from ~~the exercise of outstanding warrants and stock options. These plans are subject to market conditions and reliance on third parties, and there is no assurance that effective implementation of~~ our **ATM Agreement** ~~plans will result in the necessary funding to continue current operations~~. We have implemented cost- saving initiatives, including delaying and reducing certain research and development programs and commercialization efforts and elimination of certain staff positions. We have concluded that our plans do not alleviate the substantial doubt about our ability to continue as a going concern beyond one year from the date the consolidated financial statements are issued. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations, and prospects. As a result of changes in the macro environment, including those resulting from geo- political actions, such as the U. S. and foreign government responses to ~~the~~ ongoing **global** conflicts ~~between Ukraine and Russia and Israel and Palestine~~, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our financing 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. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business, financial condition, results of operations, and prospects, and could require us to delay or abandon clinical development plans. In addition, one or more of our current CROs, clinical investigators, third-party vendors and clinical sites, and other suppliers may not survive an economic downturn, which could directly affect our ability to achieve our operating goals within our desired timeline and budget **. Additionally, political conditions, including new and changing laws or tariffs, regulations, government funding, executive orders and enforcement priorities, may create uncertainty about how such laws and regulations will be interpreted and applied, which may adversely impact our business. For example, changes in the regulatory environment affecting life sciences and pharmaceutical companies, and reduced budget allocations to government agencies that fund research and development activities, such as the NIH, or targeted cancellations by the U. S. federal government of certain grants or contracts, could adversely affect our business or results of operations** . We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance. We are a biopharmaceutical company formed in December 2012 focusing on the discovery and development of innovative drugs for the treatment of neurological diseases and other disorders. Our limited operating history, particularly in light of the rapidly evolving nanocrystal therapies field, may make it difficult to evaluate our current business and predict our future performance. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential drug candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. As a relatively new business, we have not yet demonstrated an ability to manufacture drugs at a commercial scale, to arrange for a third party to do so on our behalf, or to conduct sales and marketing activities necessary for successful commercialization. We have not had any product approved for commercial sale and have not generated any revenue from product sales. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early- stage biopharmaceutical companies in rapidly evolving fields. Consequently, any assessment you make about our current business or future success or viability may not be as accurate as it could be if we had a longer operating history and had been able to reduce some of the uncertainties as set out above. Further, our limited financial track record, without any revenue yet from our expected future principal business, may be of limited reference value for your assessment of our business. We may encounter difficulties in managing our growth and expanding our operations successfully, which could adversely affect our business, financial condition, results of operations, and prospects. As we seek to advance our drug candidates through clinical trials, we will need to expand our development, regulatory, compliance, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of our management. Our future financial performance and our ability to commercialize our drug candidates, if approved, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional clinical, regulatory, manufacturing, financial, legal, managerial, administrative, and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successful growth and could harm our business, financial condition, results of operations, and prospects. Changes in government regulation or in practices relating to the pharmaceutical and biotechnology industries, including potential healthcare reform, could decrease the need for our drug candidates, or make it more difficult to obtain regulatory approvals for our drug candidates and commercialize them. In recent years, the U. S. Congress, the President, executive branch agencies, and state legislatures have considered various types of healthcare reform to control growing healthcare costs. Similar reform movements have occurred in parts of Europe and Asia. Healthcare reform legislation could also increase the costs of drug development and commercialization or limit reimbursement for marketed drugs that could limit the profits to be made from the development of new drugs. This could adversely affect research and development expenditures by pharmaceutical and biotechnology companies, which could in turn decrease the business opportunities available to us in the U. S. and other countries. We are unable to predict what reform proposals will be adopted in the future, if any. If we, or any CRO we may engage, fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition, results of operations, and prospects. We and certain of the third parties we contract with, such as our third- party CROs, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. In addition, our future construction projects may necessitate that certain regulatory procedures be completed with the relevant administrative authorities in charge of environmental protection, health and safety before the project can be put into operation. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot entirely eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Although we maintain workers' compensation insurance to cover the costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials. In addition, the environmental, health and safety laws and regulations applicable to us and our third- party contractors may change and impose stricter requirements in the

future. As a result, we may be required to incur substantial costs to comply with future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Our internal computer systems, or those used by any CROs or other third- party contractors or consultants we may engage, may fail or suffer security breaches. Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although, to our knowledge, we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and business operations. In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on- site systems and outsourced vendors. These applications and data encompass a wide variety of business- critical information including research and development information, commercial information, and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions of our systems or those of the vendors that provide information systems, networks or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial- of- service attacks and other malicious activity, as well as security incidents from inadvertent or intentional actions (such as error or theft) by our employees, contractors, consultants, business partners, and / or other third parties, supply chain attacks, power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events. We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in our information systems and networks and those of our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and / or systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing and other cyber- attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. We may also be required to comply with laws, regulations, rules, industry standards, and other legal obligations that require us to maintain the security of personal data. We may also have contractual and other legal obligations to notify customers, collaborators, or other relevant stakeholders of security incidents. Failure to prevent or mitigate cyberattacks could result in unauthorized access to data, including proprietary and personal information. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security breaches involving certain types of data. Such disclosures are costly, could lead to negative publicity, may cause our customer or collaborators or other relevant stakeholders to lose confidence in the effectiveness of our security measures and require us to expend significant capital and other resources to respond to and / or alleviate problems caused by the actual or perceived security incident. In addition, the costs to respond to a cybersecurity event or to mitigate any identified security vulnerabilities could be significant, including costs for remediating the effects of such an event, paying a ransom, restoring data from backups, and conducting data analysis to determine what data may have been affected by the breach. In addition, our efforts to contain or remediate a security incident or any vulnerability exploited to cause an incident may be unsuccessful, and efforts and any related failures to contain or remediate them could result in interruptions, delays, harm to our reputation, and increases to our insurance coverage. In addition, regulatory response or litigation resulting from security breaches may adversely affect our business. Unauthorized access to our information technology systems could result in litigation with our customers, collaborators, or other relevant stakeholders, or regulatory actions by government entities. These proceedings could force us to spend money in defense or settlement, divert management' s time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices in response to such litigation, which could have an adverse effect on our business. If a security breach were to occur and the confidentiality, integrity or availability of our data or the data of our collaborators were disrupted, we could incur significant liability, which could negatively affect our business and damage our reputation. Furthermore, 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, or at all, and losses we could incur to respond to and remediate a security breach. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not

deny coverage as to any future claim. We manufacture all of our drug candidates ourselves, and intend to manufacture most, if not all, of any approved drugs ourselves as well, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. We currently have manufacturing facilities in the U. S. and may build additional manufacturing facilities in other markets to expand our manufacturing capacity. These facilities may encounter unanticipated delays and expenses due to a number of factors, including regulatory requirements. If construction, regulatory evaluation, and / or approval of our new facilities is delayed, we may not be able to manufacture sufficient quantities of our drug candidates, if approved, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could require us to raise additional funds from other sources, which may not be available on favorable terms or at all. Much of the equipment used in our manufacturing process was developed and built by us, and it would be difficult or even impossible to purchase or create suitable replacements in a short period of time. Further, for much of this equipment we have an insufficient amount of or no spare parts available. Were certain equipment, some of which is critical to the production of our drug candidates, to become damaged, lost, or otherwise unusable, we would have to construct new parts, which could take a considerable amount of time, causing a temporary halt to at least a portion of our production operations. Additionally, we are constantly seeking to further fine- tune and develop our advanced manufacturing techniques and process controls to fully utilize our facilities. Advances in manufacturing techniques may render our facilities and equipment inadequate, in which case we may lose any competitive advantage. To produce our drug candidates in the quantities that we believe will be required to meet anticipated market demand, if approved, we will need to increase or " scale up " the production process by a significant factor over current levels of production. A significant part of the scaling up process will include seeking ways to increase the automation and semi- automation of our production process, which will require additional research and development, investment, potential new regulatory approvals, and cooperation with third parties, some of which may not be successful. If we are unable or are delayed in scaling up, or if the cost of doing so is not economically feasible for us, we may not be able to produce our approved drug candidates in a sufficient quantity to meet any future demand. Delays in completing and receiving regulatory approvals for our manufacturing facilities could delay our development plans or commercialization efforts, which could harm our business. Our manufacturing facilities will be subject to ongoing, periodic inspection by various regulatory authorities, including the FDA, EMA, China' s National Medical Products Administration (" NMPA "), Health Canada, and the Australian Therapeutics Goods Administration (" TGA ") or other comparable regulatory agencies to ensure compliance with GMP. Our failure to follow and document our adherence to such GMP or other regulatory requirements may lead to significant delays in the availability of products for clinical or, if approved, commercial use, and may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or the commercialization of our drugs, if approved. We also may encounter problems with the following: ● achieving adequate or clinical- grade materials that meet FDA, EMA, NMPA, Health Canada, TGA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs; ● shortages of qualified personnel, raw materials or key contractors; and ● ongoing compliance with GMP and other requirements of the FDA, EMA, NMPA, Health Canada, TGA or other comparable regulatory agencies. Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures, or recalls of our drug candidates, operating restrictions and civil or criminal prosecutions, any of which could harm our business. Damage to, destruction of, or interruption of production at our manufacturing facilities would negatively affect our business and prospects. If our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time- consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval before selling any of our drugs, if approved, manufactured at that new facility. Such an event could delay our clinical trials or reduce our product sales if any of our drug candidates are approved and successfully commercialized. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. Any disruption that impedes our ability to manufacture our drug candidates in a timely manner could materially harm our business, financial condition, results of operations, and prospects. Currently, we maintain insurance coverage against damage to our property and equipment in amounts we believe are reasonable. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet the requirements for our drug candidates if there were a catastrophic event or failure of our manufacturing facilities or processes. Significant or sustained inflation could adversely affect our business, financial condition and results of operations. Inflation can adversely affect us by increasing our costs, including salary costs. Significant inflation is often accompanied by higher interest rates. Any sustained inflation or significant increases in inflation and interest rates could have a material adverse effect on our business, financial condition and results of operations. ~~Increases in interest rates may also adversely affect the repayment terms of certain of our debt agreements.~~ Our future success depends on our ability to retain key executives and to attract, train, retain, develop, and motivate qualified and highly skilled personnel. We are highly dependent on Mark Mortenson, our co- founder and Chief Science Officer, Rob Etherington, our Chief Executive Officer **(" CEO ")** and President, and the other principal members of our management and scientific teams. We do not maintain " key person " insurance for any of our executives or other employees. The loss of the services of any of our executive officers, other key employees, and other scientific advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. Recruiting, retaining, and developing qualified scientific, technical, clinical, manufacturing, sales, and marketing personnel in the future will also be

critical to our success. In addition, we rely on third- party consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, clinical development, operations, and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development, and commercialization objectives and seriously harm our ability to successfully implement our business strategy. We benefit from certain tax and financial incentives, the expiration of or changes to which could adversely affect our profitability. We benefit from certain tax treatments, as well as tax concessions in relation to our research and development costs. We receive refundable tax credits through the research and development tax credits in the U. S., Australia, and the state of Maryland. In the U. S., the research and development tax credit is used to offset federal employment taxes on our U. S. payroll. In Australia, we receive a refundable tax offset of eligible research and development activities equal to our corporate tax rate plus 18 %. In Maryland, we receive the Basic Research and Development Tax credit, which is used to offset state income taxes and may be applied against following years' taxes until the credit is used or the credit may be carried forward for seven years. We also receive a tax exemption in Maryland for state personal property and sales tax, as well certain tax credits. In addition, current or future tax treatments, tax concessions, tax allowances and financial incentives applicable to us may be changed, terminated, or otherwise become unavailable due to many factors, including changes in government policy or administrative decisions by the relevant government authorities. Due to potential changes in government policies, we cannot be certain of the level of government grants we will receive in the future. Our post- tax profitability and cash flows may be adversely affected as a result of one or more of these or other factors. Our ability to use net operating losses to offset future taxable income may be subject to certain limitations. We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any. As of December 31, ~~2023~~ **2024**, we had U. S. federal net operating loss (" NOL ") carryforwards of $ ~~147~~ **170**. 1 million, of which $ ~~113~~ **136**. 7 million may be carried forward indefinitely to reduce future taxable income but utilization is limited to 80 % of our annual taxable income in any given year based on current federal tax laws. The remaining balance of $ 33. 4 million will begin to expire after 2034. As of December 31, ~~2023~~ **2024**, we had state NOL carryforwards of $ ~~96~~ **116**. ~~7~~ **1** million, of which $ ~~83~~ **103**. ~~7~~ **2** million may be carried forward indefinitely to reduce future taxable income but utilization is limited to 80 % of our taxable income in any given tax year based on current tax laws. The remaining balance of $ 12. 9 million will begin to expire after 2032. As of December 31, ~~2023~~ **2024**, we had research and development tax credit carryforwards of $ ~~5.~~ 6 **. 4** million, which may be available to reduce future tax liabilities and expire at various dates beginning after 2032. Under U. S. federal tax legislation commonly referred to as the Tax Cuts and Jobs Act (" TCJA "), as modified by the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, U. S. federal NOLs incurred in taxable years beginning after December 31, 2017 and in future taxable years may carry forward indefinitely, but the deductibility of such U. S. federal NOLs incurred in taxable years beginning after December 31, 2020 are limited. It is uncertain how various states will respond to the TCJA and CARES Act. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 % change, by value, in its equity ownership over a three- year period, the corporation' s ability to use its pre- change NOL carryforwards and other pre- change tax attributes to offset its post- change income or taxes may be limited. Any future offerings of equity securities, together with other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382 of the Internal Revenue Code of 1986. We have not conducted a study to assess whether any such ownership changes have occurred. We may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it would harm our financial condition and results of operations by effectively increasing our future tax obligations. Changes in tax laws may adversely affect us, and the Internal Revenue Service or a court may disagree with tax positions taken by us, which may result in adverse effects in our financial condition or the value of our Common Stock. The TCJA, enacted on December 22, 2017, significantly affected U. S. tax law, including by changing how the U. S. imposes tax on certain types of income of corporations and by reducing the U. S. federal corporate income tax rate to 21 %. It also imposed new limitations on a number of tax benefits, including deductions or business interest, use of net operating loss carry forwards, taxation of foreign income and the foreign tax credit, among others. The CARES Act, enacted on March 27, 2020, in response to the COVID- 19 pandemic, further amended the Internal Revenue Code of 1986, including in respect of certain changes that were made by the TCJA, generally on a temporary basis. In addition, the Internal Revenue Service (" IRS ") has yet to issue guidance on a number of important issues regarding the changes made by the TCJA and the CARES Act. In the absence of such guidance, we will take positions with respect to a number of unsettled issues. There is no assurance that the IRS or a court will agree with the positions taken by us, in which case tax penalties and interest may be imposed that could adversely affect our business, cash flows or financial performance. Additionally, the current administration may propose significant changes to U. S. tax law, some or all of which may be enacted. The passage of such legislation, as well as changes or modifications in existing judicial decisions or in the current positions of the IRS, could substantially modify the tax treatment described in this Annual Report, possibly on a retroactive basis. We cannot predict whether the U. S. Congress or any other legislative body will enact new tax legislation or whether the IRS or any other tax authority will issue new regulations or other guidance, nor can we predict what effect such legislation or regulations might have on us or our financial condition. There can be no assurance that future tax law changes will not increase the rate of the corporate income tax significantly, impose new limitations on deductions, credits or other tax benefits, or make other changes that may adversely affect our business, cash flows or financial performance. Our business and operations have been affected by and could be materially and adversely affected in the future by the effects of health epidemics and pandemics, which could also cause material adverse effects on the business and operations of third parties on which we rely. Our business and operations could be adversely affected by health epidemics and pandemics. We, our CROs, clinical investigators, third- party vendors and clinical sites, and other suppliers may experience

disruptions in supply of drug candidates and / or procuring items that are essential for our research and development activities, including raw materials used in the manufacturing of our drug candidates, medical and laboratory supplies used in our clinical trials or preclinical studies or animals that are used for preclinical testing, in each case, for which there may be shortages due to future epidemics and pandemics. Any disruption in the supply chain from any potential future epidemics and pandemics could have a material adverse effect on our clinical trial plans and business operations. We and our third- party CROs have faced disruptions that affected our ability to initiate and complete preclinical studies, caused manufacturing disruptions, and created delays at clinical trial site initiation and clinical trial enrollment, which ultimately led to the early conclusion of a clinical trial. Even if clinical trial sites are actively recruiting, we may face difficulties recruiting or retaining patients in our ongoing and planned clinical trials if patients are affected by or are fearful of visiting or traveling to clinical trial sites because of any potential future epidemics and pandemics. Prolonged delays or closure to enrollment in our trials or patient discontinuations could have a material adverse impact on our clinical trial plans and timelines. Any negative impact from health epidemics or pandemics on the ability of clinical trial sites to recruit or retain patients or collect patient data could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and, if approved, to commercialize our drug candidates, increase our operating expenses, and have a material adverse effect on our financial results. The response to health epidemics and pandemics may redirect our resources with respect to regulatory and intellectual property matters in a way that would adversely affect our ability to obtain regulatory approvals and protect our intellectual property. In addition, we may face impediments to regulatory meetings and approvals due to measures intended to limit in- person interactions. Health epidemics and pandemics may materially and adversely affect us economically. While the potential global economic impact brought by, and the duration of, health epidemics and pandemics may be difficult to assess or predict, they have caused and could cause future disruption in the global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could negatively affect our liquidity in the future. The ultimate impact of potential future epidemics or pandemics is highly uncertain and subject to continued change. These effects could have a material impact on our business and operations, or the businesses and operations of third parties on which we rely. We have identified material weaknesses in our internal control over financial reporting. If we fail to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our Common Stock. Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404 of the Sarbanes- Oxley Act or any subsequent testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our internal control over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our Common Stock. In connection with the audit of our financial statements as of and for the years ended December 31, **2024 and** 2023 ~~and 2022~~ , our management identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses identified relate to the fact that we did not design or maintain an effective control environment commensurate with our financial reporting requirements. This deficiency in our control environment contributed to the following additional material weaknesses related to control activities and information and communication within our internal control over financial reporting: ● we did not design and maintain controls over the preparation and review of account reconciliations and the review and segregation of duties over manual journal entries, including controls over the completeness and accuracy of information; and ● we did not design and maintain information technology (“ IT ”) general controls for IT systems that are relevant to the preparation of the financial statements. Specifically, we did not design and maintain: (a) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs, and data to our appropriate personnel; (b) program change management controls to ensure that IT program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized, and implemented appropriately; (c) computer operations controls to ensure that data backups are authorized and monitored; and (d) testing and approval controls for program development to ensure that new software development is aligned with business and IT requirements. Each of the control deficiencies described above could result in a misstatement of one or more account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. Accordingly, our management has determined that each of the control deficiencies described above constitute material weaknesses. Although we have begun to implement measures to address the material weaknesses, the implementation of these measures may not fully address the material weaknesses and deficiencies in our internal control over financial reporting, and we cannot conclude that these matters have been fully ~~remedied~~ **remediated** . As we continue to evaluate, and work to improve, our internal control over financial reporting, management may determine that additional or different measures to address control deficiencies or modifications to the remediation plan are necessary. Further, in the future we may determine that we have additional material weaknesses. Our failure to remediate the material weaknesses or failure to identify and address any other material weaknesses or control deficiencies could result in inaccuracies in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis, which could cause investors to lose confidence in our reported financial information, which

may result in volatility in and a decline in the market price of our Common Stock. Pursuant to Section 404, after the Reverse Recapitalization, we, as the surviving entity, are required to furnish a report by our management on the effectiveness of our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. **We** ~~To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we~~ will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm, if and when required, will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could adversely affect investor confidence in us and, as a result, the value of our Common Stock. There is significant uncertainty associated with our drug candidates and their viability as a commercial product. Metallic nanocrystal therapeutic candidates, such as our lead drug candidate, CNM- Au8, are considered emerging and novel investigational products for the potential treatment of neurological diseases and other disorders. We are developing CNM- Au8 for the treatment of neurological disorders such as ALS, MS, and PD through remyelination and / or neuroprotection mechanisms related to catalysis of certain biological reactions. There are currently no approved remyelination therapies and the evidence for an effect of neuroprotection treatments on these indications is thus far limited. Since there is limited clinical trial data and precedent for the development of nanocrystal therapies that promote remyelination and neuroprotection to treat these indications, there is a substantial risk that the design or outcomes of our clinical trials will not be satisfactory to support regulatory approval. In addition, there are generally limited or no regulatory precedents concerning metallic nanocrystal drug marketing authorization, or a regulatory framework to appropriately differentiate approved nanocrystal product labeling. Our lead metallic nanocrystal drug candidate, CNM- Au8, contains nanocrystals made entirely of high purity gold alone. It is unclear how regulatory authorities will identify or classify the active moiety of CNM- Au8, including whether it is classified as a new chemical entity or comparable designation. The inability to obtain sufficiently differentiated active moiety classification from gold generically could potentially limit CNM- Au8 and our drug candidates from ever achieving profitability. Moreover, the mechanisms of action for nanocrystal therapies are not thoroughly understood, and adverse events or side effects may be observed in clinical trials and reported by medical practitioners in connection with patient usage in the future. If those adverse events or side effects prove significant, they may hamper the ability of our drug candidates to pass through clinical trials or they may outweigh the benefits that patients derive from using our drug candidates, both of which could potentially prevent our drug candidates from ever achieving profitability. Our drug candidates are not metabolized and may accumulate in the body following long- term usage, making the long- term effects of taking our drug candidates for substantial periods of time uncertain. While all of the current toxicology studies of our drug candidates have resulted in no- adverse- effect levels as of the date of this Annual Report, we have not completed reproductive or carcinogenicity studies, which we are required to complete in the future. Any negative results from these studies could materially and adversely affect our business, results of operations, financial condition, and prospects. Moreover, the results of clinical trials for nanocrystal therapies could reveal a high and unacceptable severity and prevalence of undesirable side effects. Any such side effects could adversely impact our ability to obtain regulatory approvals. For example, the FDA, NMPA, Health Canada, TGA, EMA or other comparable authorities could order us to suspend or terminate our studies or to cease further clinical development of or deny approval of our drug candidates. In addition, any adverse drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete trials or may result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations, and prospects significantly. We have not previously obtained any regulatory approval for a drug candidate and we may be unable to obtain or may be delayed in obtaining regulatory approval for any of our drug candidates. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize drug candidates in a timely manner. We cannot commercialize drug candidates without obtaining regulatory approval to market each drug from the FDA, NMPA, Health Canada, TGA, EMA and other comparable regulatory authorities. The time required to obtain approval from regulatory authorities is unpredictable but typically takes years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate' s clinical development and may vary among jurisdictions. Our drug candidates could fail to receive regulatory approval for many reasons, including: ● failure to begin or complete clinical trials due to disagreements with regulatory authorities; ● failure to begin or complete clinical trials due to inability to recruit sufficient numbers of study participants; ● failure to demonstrate that a drug candidate is safe and effective or is safe, pure and potent for our proposed indication; ● failure of clinical trial results to meet the level of statistical significance required for approval; ● data integrity issues related to our clinical trials; ● disagreement with our interpretation of data from preclinical studies or clinical trials; ● changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval or require us to amend our clinical trial protocols; ● regulatory requests for additional analysis, reports, data, nonclinical studies and clinical trials, or questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates; ● insufficient data from the clinical trials of our drug candidates to obtain regulatory approval; ● failure by us or our investigators to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and ● clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory

requirements, or dropping out of a trial. The FDA, NMPA, TGA, Health Canada, EMA or a comparable regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. New or unexpected adverse events, or changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or HRECs for re- examination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in the completion of, or the termination of, a clinical trial of any of our drug candidates, the commercial prospects of that drug candidate will be harmed, and our ability to generate product sales revenues from any of those drug candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenues for that product. Any of these occurrences may harm our business, financial condition, results of operations, and prospects significantly. 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 drug candidates. We may not be able to successfully identify, discover, or develop new drug candidates. We cannot guarantee that we will be successful in identifying potential drug candidates for clinical development for a number of reasons. For example, our research methodology may be unsuccessful in identifying potential drug candidates or those we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. We have devoted significant resources to discovery efforts through our proprietary electro- crystal- chemistry drug development platform, however, we cannot guarantee that we will be successful in identifying additional potential drug candidates. Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and drug targets require substantial technical, financial, and human resources. Our research programs may initially show promise in identifying potential indications and / or drug candidates, yet fail to yield results for clinical development for a number of reasons, including: ● the research methodology used may not be successful in identifying potential indications, and / or drug candidates; ● potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or ● it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our drug portfolio. Accordingly, there is no assurance that we will ever be able to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially and adversely affect our future growth, business, financial condition, results of operations, and prospects. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful. Preclinical and clinical development of drug candidates involves a lengthy and expensive process with an uncertain outcome, and we are unable to predict if or when we will successfully develop or commercialize any of our drug candidates. There is a risk of failure for each of our drug candidates. Before obtaining regulatory approval for the sale of any of our drug candidates, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. It is difficult to predict when or if any of our drug candidates will prove effective and safe in humans or receive regulatory approval. Our internal discovery programs for some of our drug candidates are at an early stage of development and will require significant investment and regulatory approvals prior to commercialization. We are not permitted to market or promote any of our drug candidates until we receive regulatory approval from the FDA, NMPA, TGA, Health Canada, EMA or comparable regulatory authorities, and we may never receive such regulatory approval for any of our drug candidates. We could encounter regulatory delays if a clinical trial is suspended or terminated by us or, as applicable, by the IRBs or the ethics committees of the institutions in which such trials are being conducted, by the DSMB, which is an independent group of experts that is formed to monitor clinical trials while ongoing, or by the FDA, NMPA, TGA, Health Canada, EMA or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including: (1) a failure to conduct the clinical trial in accordance with regulatory requirements or the applicable clinical protocols, (2) inspection of the clinical trial operations or trial site by the FDA, NMPA, TGA, Health Canada, EMA or other regulatory authorities that results in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, (3) failure to demonstrate a benefit from using a drug, (4) changes in governmental regulations or administrative actions, or (5) lack of adequate funding to continue the clinical trial. Many of the factors that cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates. Further, the FDA, NMPA, TGA, Health Canada, EMA or other regulatory authorities may disagree with our clinical trial design or our interpretation of data from clinical trials, or may change the requirements for approval even after any regulatory authority has reviewed and commented on the design for our clinical trials. Preclinical studies and clinical trials are expensive, difficult to design and implement, and can take many years to complete. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analysis, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their drug candidates. Future clinical trials of our drug candidates may not be successful. Commencement of clinical trials is subject to finalizing the trial design based on ongoing discussions with the FDA, NMPA, TGA, Health Canada, EMA and / or other regulatory authorities. The FDA, NMPA, TGA, Health Canada, EMA and other regulatory authorities could change their position on the acceptability of trial designs or clinical endpoints, which could require us to complete additional clinical trials or impose approval conditions that we do not currently expect. Successful completion of our clinical trials is a prerequisite to submitting an NDA (or analogous filing) to the FDA, NMPA, TGA, Health Canada, EMA and / or other regulatory authorities for each drug candidate and, consequently, the ultimate approval and commercial marketing of our drug candidates. We do not know whether the clinical trials for our drug candidates will be completed on schedule, if at all. Results of earlier clinical trials

may not be predictive of results of later- stage clinical trials. The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later- stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Future clinical trial results may not be favorable for these and other reasons. In some cases, there can be significant variability in the safety and / or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen, and the rate of dropout among clinical trial participants. As drug candidates are developed through preclinical to early- to late- stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. Any of these changes could make the results of planned clinical trials or other future clinical trials we may initiate less predictable and could cause our drug candidates to perform differently, which could delay completion of clinical trials, delay approval of our drug candidates, and / or jeopardize our ability to commence commercialization of our drug candidates. Clinical trials of our drug candidates may fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities, or may not otherwise produce positive results, which may cause us to incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates. Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent us from receiving regulatory approval or commercializing our drug candidates, including: ● regulators, IRBs, or HRECs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; ● our inability to reach agreements on acceptable terms with prospective CROs, clinical trial vendors, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ● manufacturing issues, including problems with manufacturing, supply quality, compliance with GMP, or obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial; ● clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs; ● the number of patients required for clinical trials of our drug candidates may be larger than we anticipate; ● our third- party contractors, including clinical investigators, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; ● we may not investigate, may not be able to license, or may be unable to properly conduct companion diagnostic tests to identify patients who are likely to benefit from treatment with our drug candidates; ● we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks; ● regulators, IRBs or HRECs may require that we or our investigators suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including non- compliance with regulatory requirements; ● the cost of clinical trials of our drug candidates may be greater than we anticipate; ● the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and ● our drug candidates may have undesirable side effects or unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the clinical trials, or reports may arise from preclinical studies or clinical trials of other therapies that raise safety or efficacy concerns about our drug candidates. If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may (i) be delayed in obtaining regulatory approval for our drug candidates; (ii) not obtain regulatory approval at all; (iii) obtain approval for indications that are not as broad as intended; (iv) have the drug removed from the market after obtaining regulatory approval; (v) be subject to additional post- market testing requirements; (vi) be subject to restrictions on how the drug is distributed or used; or (vii) be unable to obtain reimbursement for use of the drug. Significant clinical trial delays may also increase our development costs and could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do. This could impair our ability to commercialize our drug candidates and may harm our business and results of operations. If we encounter difficulties enrolling patients in clinical trials, clinical trials of our drug candidates may be delayed or otherwise adversely affected. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until our conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including: ● any future health epidemics or pandemics; ● the size and nature of the patient population; ● the design of the trial, including the patient eligibility criteria defined in the protocol; ● the size of the study population required for analysis of the trial' s primary endpoints; ● the proximity of patients to trial sites; ● our ability to recruit clinical trial investigators with the appropriate competencies and experience; ● competing clinical trials for similar therapies or other new therapeutics; ● clinicians' and patients' perceptions as to the potential advantages and side effects of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating; ● our ability to obtain and maintain patient consents; ● the risk that patients enrolled in clinical trials will not complete a clinical trial; and ● the availability of approved therapies that are similar in mechanism to our drug candidates. Failure of our timely completion of clinical trials would delay the approval and commercialization of our drug candidates, impair the commercial performance of our drug candidates, and consequently harm our business and results of operations. If we are not able to obtain, or experiences delays in obtaining, required regulatory approvals, we will not be able to

commercialize our drug candidates, and our ability to generate revenue will be materially impaired. Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in preclinical studies and well- controlled clinical trials, and, with respect to approval in the U. S., to the satisfaction of the FDA, that the drug candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In addition to preclinical and clinical data, the NDA must include significant information regarding the CMC for the drug candidate. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. After we submit an NDA to the FDA, the FDA decides whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. We have not yet demonstrated an ability to file for or receive regulatory approval for our drug candidates. For example, we do not have experience in preparing the required materials for regulatory submission or navigating the regulatory approval process. As a result, our ability to successfully submit an NDA and obtain regulatory approval for our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience in obtaining regulatory approvals. Regulatory authorities outside of the U. S., such as the NMPA, TGA, Health Canada and EMA, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our drug candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation, and additional administrative review periods. Seeking non- U. S. regulatory approval could require additional nonclinical studies or clinical trials, which could be costly and time consuming. The non- U. S. regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain non- U. S. regulatory approvals on a timely basis, if at all. The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly both inside and outside the U. S., and approval is never guaranteed. Even if our drug candidates were to successfully obtain approval from the regulatory authorities, any approval might significantly limit the approved indications for use, or require that precautions, contraindications or warnings be included on the product labeling, or require expensive and time- consuming post- approval clinical trials or surveillance as conditions of approval. Following any approval for commercial sale of our drug candidates, certain changes to the drug, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the FDA, NMPA, TGA, Health Canada, EMA and comparable regulatory authorities. Also, regulatory approval for any of our drug candidates may be withdrawn. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of any other drug candidate in the future. Disruptions to the normal functioning of the FDA and comparable foreign regulatory authorities and other government agencies could hinder their ability to perform and carry out important roles and activities on which the operation of our business relies, which could negatively impact our business. The ability of the FDA, NMPA, TGA, Health Canada, and EMA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result, which may continue in the future. 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 government agencies may slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Since March 2020, when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume pre- COVID- 19 pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre- approval inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the FDA has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID- 19 pandemic, a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. Regulatory authorities outside the U. S. may adopt similar restrictions or other policy measures in response to future health epidemics or pandemics and may experience delays in their regulatory activities. **Further, with the change in presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. There is also uncertainty as to how other measures being implemented by the new administration across the government will impact our activities and those of the FDA and its operations. For example, the potential loss of FDA personnel could lead to further disruptions and delays in FDA review of our product candidates. Similarly, efforts by the new administration to substantially reduce research funding by the NIH of medical research could have substantial direct or indirect impacts on our research activities.** Favorable designations may not be granted, or if granted, may be withdrawn later, for any of our drug candidates, and may not lead to faster development or regulatory review or approval. We do not currently have Fast Track Designation or Breakthrough Therapy Designation, but may seek one or more of such designations in the future. If a drug is intended for the treatment of a serious or life- threatening condition and the drug demonstrates the

potential to address unmet medical need for that condition, the drug sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion in deciding whether or not to grant this designation. Even if we believe a particular drug candidate is eligible for this designation, we cannot assure that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a development, review or approval process faster than conventional FDA procedures. The FDA may withdraw a Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Many drugs that have received Fast Track Designation have failed to obtain approval from the FDA. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development. Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe, after completing early clinical trials, that one of our drug candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead decide not to grant that designation. In any event, the receipt of a Breakthrough Therapy Designation for a drug candidate may not result in a faster development, review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our drug candidates qualify as Breakthrough Therapies, the FDA may later decide that such drug candidates no longer meet the conditions for qualification. Although we have obtained FDA orphan drug designation for CNM- Au8 for the treatment of ALS, we may not realize any benefit from such designation and it does not increase the chance of approval. The FDA granted orphan drug designation to our lead drug candidate, CNM- Au8, for the treatment of ALS in May 2019. Regulatory authorities in some jurisdictions, including the U. S. and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a disease with a patient population of fewer than 200, 000 individuals in the U. S., or that affects more than 200, 000 individuals in the U. S. and for which there is no reasonable expectation that costs of research and development of the product for the indication can be recovered by sales of the product in the U. S. Generally, if a drug with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or EMA, from approving another marketing application for the same drug for the same indication during the period of exclusivity. The applicable period is seven years in the U. S. and ten years in the European Union. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Although we have obtained orphan drug designation for CNM- Au8 for the treatment of ALS in the U. S., and may obtain the same designation for other drug candidates or indications, that designation may not effectively protect the drug candidate from competition, if approved, because different drugs can be approved for the same condition and the same drugs can be approved for a different condition but used off- label for any orphan indication we may obtain. Even after an orphan drug is approved, the FDA can subsequently approve a drug that is otherwise the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective, or makes a major contribution to patient care. Any of our drug candidates, if approved, would continue to be subject to ongoing or additional regulatory obligations and regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates. Any of our drug candidates, if approved, will be subject to ongoing or additional regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- market studies, and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the U. S. and requirements of comparable regulatory authorities in the European Union, China, Australia and other markets. Manufacturers and manufacturers' facilities are required to comply with extensive FDA, NMPA, TGA, Health Canada, EMA and other comparable regulatory authority requirements ensuring that quality control and manufacturing procedures conform to GMP. As such, we will be subject to continual review and inspections to assess compliance with GMP and adherence to commitments made in any NDA, other marketing applications, and previous responses to any inspection observations if we were to build manufacturing facilities in the future. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. Any approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, which could adversely affect the drug' s commercial potential or contain requirements for potentially costly post- market testing and surveillance to monitor the safety and efficacy of the drug candidate. The FDA, NMPA, TGA, Health Canada, EMA or a comparable regulatory authority may also require a risk evaluation mitigation strategy program as a condition of approval of our drug candidates or following approval. In addition, if the FDA, NMPA, TGA, Health Canada, EMA or a comparable regulatory authority approves our drug candidates, we will have to comply with requirements, including, for example, submissions of safety and other post- market information and reports, registration, as well as continued compliance with GMP and GCP, for any clinical trials that we conduct post- approval. The FDA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The FDA, NMPA, TGA, Health Canada, EMA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant penalties

and enforcement actions. Even if we are able to commercialize any approved drug candidates, the drugs may become subject to national or other third- party reimbursement practices or unfavorable pricing regulations, which could harm our business. The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. In Europe, Canada, Australia, China, and some markets outside China, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact our revenues. Our ability to commercialize any approved drug candidates successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers, and other organizations. A primary trend in the global healthcare industry is cost containment. Government authorities and these third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In the U. S., no uniform policy of coverage and reimbursement for drugs exists among third- party payors. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third- party payor is a time- consuming and costly process that could require us to provide to each payor supporting scientific, clinical, and cost- effectiveness data for the use of our future approved drugs on a payor- by- payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co- payments that patients find unacceptably high. Additionally, third- party payors may not cover, or provide adequate reimbursement for, long- term follow- up evaluations required following the use of our future approved drug candidates. Patients are unlikely to use any of our future approved drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the drug. Because some of our drug candidates may have a higher cost of goods than conventional small molecule therapies, and may require long- term follow- up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. Increasingly, third- party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot assure that reimbursement will be available for any approved drug candidate that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any approved drug candidate that we commercialize. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate that we successfully develop. There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the purposes for which the drug candidates are approved by the FDA, NMPA, TGA, Health Canada, EMA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U. S. Our inability to promptly obtain coverage and profitable payment rates from both government- funded and private payors for any future approved drug candidates and any new drugs that we develop could have a material adverse effect on our business, operating results and overall financial condition. We intend to seek approval alone or in conjunction with partners to market our drug candidates in the U. S., China, the European Union, Australia, Canada, and other jurisdictions. In China, Australia, Canada, and the European Union, the pricing of drugs is subject to governmental control, and it can take considerable time after obtaining marketing regulatory approval to get the future approved drugs reimbursed. Market acceptance and sales of any of our future approved drug candidates will depend significantly on the availability of adequate coverage and reimbursement from third- party payors for drugs and may be affected by existing and future healthcare reform measures. Our drug candidates, if approved in the future, may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success and the market opportunity for the drug candidate may be smaller than we estimate. Our drug candidates, if approved in the future, may fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. For example, current MS treatments are well established in the medical community, and physicians may continue to rely on these treatments to the exclusion of our drug candidates that are in clinical trials for the same or similar indications. In addition, physicians, patients, and third- party payors may prefer other novel products to ours. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant product sales revenues and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including: ● the clinical indications for which our drug candidates are approved; ● whether physicians, hospitals, treatment centers and patients consider our drug candidates as a safe and effective treatment; ● the potential and perceived advantages of our drug candidates over alternative treatments; ● the prevalence and severity of any side effects; ● product labeling or product insert requirements of regulatory authorities; ● limitations or warnings contained in the labeling approved by regulatory authorities; ● the timing of market introduction of our drug candidates as well as competitive drugs; ● the cost of treatment in relation to alternative treatments; ● the availability of adequate coverage, reimbursement and pricing by third- party payors and government authorities; ● the willingness of patients to pay out- of- pocket in the absence of coverage and reimbursement by third- party payors and government authorities; and ● the effectiveness of our sales and marketing efforts. If any approved drug candidates that we commercialize fail to achieve market acceptance among physicians, patients, hospitals, treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if any future approved drug candidates achieve market acceptance, we may not be

able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our drug candidates, are more cost- effective or render our drug candidates obsolete. If our drug candidates cause, or are perceived to cause, undesirable side effects, it can result in delays or failure to receive regulatory approval or limitations on the commercial profile of an approved label. Undesirable side effects caused by our drug candidates could cause either 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, NMPA, TGA, Health Canada, EMA or other regulatory authorities. If the results of the ongoing clinical trials of our drug candidates reveal a high and unacceptable severity and prevalence of undesirable side effects, the clinical trials of our drug candidates could be suspended or terminated and the FDA, NMPA, TGA, Health Canada, EMA or comparable regulatory authorities could order us to cease further development of or deny approval of our drug candidates for any or all targeted indications. The drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, and prospects significantly. Clinical trials assess a sample of the potential patient population. With a limited number of patients and a limited duration of exposure, rare and severe side effects of our drug candidates may only be uncovered with a significantly larger number of patients exposed to the drug candidates. If our drug candidates receive regulatory approval and we or others discover undesirable side effects caused by such drugs (or any other similar drugs) or that such drug candidates are less effective than previously believed, a number of potentially significant negative consequences could result, including: ● the FDA, NMPA, TGA, Health Canada, EMA or other comparable regulatory authorities may withdraw or limit their approval of such drug candidates; ● the FDA, NMPA, TGA, Health Canada, EMA or other comparable regulatory authorities may require the addition of labeling statements, such as a " boxed " warning or a contra- indication; ● we may be required to create a medication guide outlining the risks of such side effects for distribution to patients; ● we may be required to change the way such drug candidates are distributed or administered, conduct additional clinical trials or change the labeling of our drug candidates; ● the FDA, NMPA, TGA, Health Canada, EMA or other comparable regulatory authorities may require the development of risk evaluation and mitigation strategies and plans to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools; ● we may be subject to regulatory investigations and government enforcement actions; ● we may decide to, or be required to, remove such drug candidates from the marketplace; ● we could be sued and held liable for injury caused to individuals exposed to or taking our drugs; and ● our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected drug candidates and could substantially increase the costs of commercializing our drugs, if approved, and significantly impact our ability to successfully commercialize our drugs and generate revenue. Adverse drug reactions and negative results from off- label use of our products could materially harm our business reputation, product brand name, commercial operations, financial condition, including the value of our Common Stock, and expose us to liability. Products distributed or sold in the pharmaceutical market may be subject to off- label drug use. Off- label drug use is prescribing a product for an indication, patient population, dosage strength or frequency, or other condition of use that is not in accordance with regulatory approved usage and labeling. Even though the FDA, NMPA, TGA, Health Canada, EMA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off- label use, there remains the risk that our products are subject to off- label drug use and are prescribed in a patient population or dosage that has not been approved by competent authorities. Off- label use of our products may be less effective or entirely ineffective and may cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm our business reputation, product brand name, commercial operations, and financial condition, including the value of our Common Stock. In addition, this may negatively impact our ability to commercialize our products because it could influence third party payers reimbursement and formulary placement decisions about our products. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approval for our drug candidates. Off- label use of our products could expose us to government investigation or prosecution. Regulatory bodies that enforce laws and regulations to prohibit off- label use may investigate whether our products are being used off- label. Even though we take steps to prevent off- label promotion of our products, this would not necessarily prevent regulatory or prosecuting agencies from investigating and taking action against us as if we were engaged in off- label promotion. As a company, we have no experience in launching and marketing drugs. If we are unable to develop sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements or arrangements with third parties, we may not be successful in commercializing any drugs, if approved, or generating drug candidate sales revenue. We have not yet demonstrated an ability to launch and commercialize any of our drug candidates, if approved. As a result, our ability to successfully commercialize any approved drugs may involve more inherent risk, take longer, and cost more than it would if we were a company with prior experience launching and marketing drugs. We will have to compete with other pharmaceutical and biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. We must either develop internal sales, marketing, and commercial distribution capabilities for any or all of our approved drugs or pursue collaborative arrangements regarding the sales and marketing of our approved drugs. However, there can be no assurance that we will be able to develop such distribution capabilities or establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales, if approved, may be lower than if we had commercialized any approved drugs by ourselves or we may fail to generate any product sales revenue in the future at all. We face substantial competition from other pharmaceutical and biotechnology companies, and our operating results may suffer if we fail to compete effectively. The development and commercialization of new drugs is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. There are a number of large pharmaceutical and

biotechnology companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of neurological diseases and other disorders for which we are commercializing our drugs or developing our drug candidates. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing, and commercialization. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any drugs that we may commercialize or may develop. Our competitors may also obtain approval from the FDA, NMPA, TGA, Health Canada, EMA or other comparable regulatory authorities for their drugs more rapidly than we may obtain approval for our drugs, which could result in our competitors establishing a strong market position before we are able to enter the market and / or could slow our regulatory approval. Many of our current or future competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller 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 acquiring technologies complementary to, or necessary for, our programs. We may be subject, directly or indirectly, to applicable anti- kickback, false claims laws, physician payment transparency laws, privacy and security laws, fraud and abuse laws or similar healthcare and security laws and regulations in the U. S. and other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain FDA approval for any of our drug candidates and begin commercializing those drugs in the U. S., our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti- Kickback Statute, the federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. Restrictions under applicable federal and state healthcare laws and regulations include the following: ● the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act; ● the federal false claims and civil monetary penalties laws, including the civil False Claims Act and the Civil Monetary Penalties Law, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; ● ~~HIPAA~~ **Other federal criminal anti- fraud statutes** ~~prohibits~~ **prohibit** , among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti- Kickback Statute, 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; ● HIPAA, as amended by HITECH, and their implementing regulations, also imposes obligations, including mandatory contractual terms, certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates and covered subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information with respect to safeguarding the privacy, security and transmission of **certain** individually identifiable health information; and ● the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to annually report to the CMS information regarding payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers **were** ~~also will be~~ required to **start** ~~report~~ **reporting** such information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists and certified nurse-midwives. The information reported is publicly available on a searchable website, with disclosure required annually. Additionally, we are subject to state and non- U. S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply to healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and / or other voluntary industry codes of conduct. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements, and if we fail to comply with applicable state law requirements, we could be subject to penalties. Violations of fraud and abuse laws may be punishable by criminal and / or civil sanctions, including penalties, fines and / or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the

U. S. government. Neither the U. S. government nor the U. S. courts have provided definitive guidance on limitations to potential liability under the fraud and abuse laws as they may apply to our business. Law enforcement authorities are increasingly focused on enforcing these laws, often using new and creative legal theories, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Regardless of the compliance efforts, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. In addition, private individuals have the ability to bring actions on behalf of the U. S. government under the federal False Claims Act as well as under the false claims laws of several states. If any such actions are instituted against us, defending against such actions, even if successful, would distract us and our key personnel from our core mission and impose potentially significant costs. If we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our approved drugs outside the U. S. will also likely subject us to non- U. S. equivalents of the healthcare laws mentioned above, among other non- U. S. laws, as well as the U. S. Foreign Corrupt Practices Act. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business. We may face difficulties from changes to current regulations and future legislation. In the U. S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of drug candidates, restrict or regulate post- approval activities, and affect the ability to profitably sell drug candidates for which marketing approval is obtained. Among policy makers and payors in the U. S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access. In the U. S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the Affordable Care Act provisions of importance to the pharmaceutical and biotechnology industries are the following: among other things, subjected biological products to potential competition by lower- cost biosimilars, created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70 % point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D. ~~Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been legal and political challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021 the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. Further, prior to the U. S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and remained open through August 15, 2021. 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 Affordable Care Act. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.~~ Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, included aggregate reductions to Medicare payments to providers of 2 % per fiscal year, which went into effect beginning on April 1, 2013, with COVID- 19 relief legislation suspending the 2 % Medicare sequester from May 1, 2020 through December 31, 2021. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Moreover, the Inflation Reduction Act of 2022 may impact existing Medicare programs that cover prescription drugs. In addition to other relevant provisions, the Inflation Reduction Act of 2022 allows the Medicare program to directly negotiate the price of certain high- expenditure prescription drugs covered under Medicare Parts B and D, starting in the year 2028 and 2026, respectively, by setting certain " maximum fair prices. " Moreover, the Inflation Reduction Act of 2022 requires manufacturers to pay rebates to the federal government if prices of certain drugs covered under the Medicare program rise faster than the rate of inflation. Additionally, there has been

increasing legislative and enforcement interest in the U. S. with respect to specialty drug pricing practices. Specifically, there have been several recent U. S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Congress has indicated that it will continue to seek new legislative and / or administrative measures to control drug costs. Additionally, **in an** ~~based on a recent~~ executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. In response to Biden' s executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance ~~these principles. No legislation or administrative actions have been finalized to implement~~ these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. Individual states in the U. S. have also become increasingly active in passing legislation and implementing regulations designed to control biopharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We anticipate that the Affordable Care Act, if substantially maintained in its current form, will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. Further, the implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from drug candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop drug candidates. Any failure to perform proper quality control and quality assurance would have a material adverse effect on our business and financial results. The manufacturing of our drug candidates and any drugs, if approved, is subject to applicable laws, regulations, and GMP. These regulations govern manufacturing processes and procedures, including record keeping and the implementation and operation of quality management systems to control and assure the quality of investigational products and products approved for sale. We apply stringent quality controls at each stage of our production process to comply with these requirements. We perform extensive tests throughout the manufacturing processes to ensure the safety and effectiveness of our drug candidates. We may, however, detect instances in which an unreleased product was produced without adherence to our manufacturing procedures or the raw material used in our production process was not collected to store in accordance with the GMP or other regulations, resulting in a determination that the implicated products should be destroyed. In addition, if we fail to comply with relevant quality control requirements under laws, regulations, and GMP, we could experience a disruption in the supply of our products, which could delay or prevent further sales of such products, which could have a material adverse effect on our business and financial results. In addition, quality issues may arise during scale- up activities. If we are unable to successfully ensure consistent and high quality of our products during large- volume production, the sales of our products may not be able to be promoted, which could have a material adverse effect on our business and financial results. We may explore the licensing of commercialization rights or other forms of collaboration worldwide, which will expose us to additional risks. Non- U. S. markets are an important component of our growth strategy. We initially intend to focus on opportunities in the U. S., the European Union, Canada, Australia, Japan, Korea and China, in particular. If we fail to obtain licenses or enter into collaboration arrangements with third parties in these or other markets, or if these arrangements are not successful, our revenue- generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including: ● efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing, and distribution efforts may increase our expenses or divert our management' s attention from the development of our drug candidates; ● difficulty of effective enforcement of contractual provisions in foreign jurisdictions; ● differing regulatory requirements for drug approvals and marketing internationally, including differing product reimbursement regimes; ● changes in a specific market' s political and cultural climate or economic condition; ● potential third- party patent rights or potentially reduced protection for intellectual property rights; ● unexpected changes in tariffs, trade barriers, and regulatory requirements; ● economic weakness, including inflation; ● compliance with tax, employment, immigration, and labor laws for employees traveling abroad; ● the effects of applicable non- U. S. tax structures and potentially adverse tax consequences; ● currency fluctuations, which could result in increased operating expenses and reduced revenue; ● production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; ● workforce uncertainty and labor unrest; ● failure of our employees and contracted third parties to comply with Office of Foreign Assets Control rules and regulations and the Foreign Corrupt Practices Act; and ● business interruptions resulting from geo- political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes, and fires. These and other risks may materially and adversely affect our ability to attain or sustain revenue from international markets and could have a material adverse effect on our business, financial condition, results of operations, and prospects. Illegal and / or parallel imports and counterfeit pharmaceutical products may reduce demand for our future approved drug candidates and could have a negative impact on our reputation and business. The imports, whether authorized by governmental policy or illegal, of competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for any of our future drugs, if approved, and, in turn, may adversely affect our sales and profitability if we commercialize our products. Unapproved foreign imports of prescription drugs are illegal under the current laws of the U. S., China, the European Union, Australia and other jurisdictions. However, illegal imports may continue to occur or even increase as the ability of patients to obtain these lower priced imports continues to grow. Furthermore, cross- border imports from lower- priced markets (parallel imports) into higher- priced markets could harm sales

of our future drugs, if approved, and exert commercial pressure on pricing within one or more markets. In addition, competent government authorities may expand consumers' ability to import lower- priced versions of our future drugs, if approved, or competing products from outside the countries where we operate. Any future legislation or regulations that increase consumer access to lower- priced medicines from outside the countries where we operate could have a material adverse effect on our business. Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or may be fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as China, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have very similar appearances to the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products can quickly erode the demand for our future drugs, if approved. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our or our collaborators' brand names. In addition, theft of inventory at warehouses, plants or while in- transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, as well as our reputation and business. We rely on third parties to conduct our preclinical studies and clinical trials and we must work effectively with collaborators to develop our drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed. We rely on and plan to continue to rely on third- party CROs and third- party vendors to monitor, collect samples, analyze samples, report data, and manage data for our ongoing preclinical and clinical programs. We rely on these third parties for execution of our preclinical studies and clinical trials. While we control only certain aspects of their activities, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We, our CROs, third- party vendors supporting our clinical programs, and our clinical investigators, are required to comply with GCPs, which are regulations and guidelines enforced by the FDA, NMPA, TGA, Health Canada, EMA, and other comparable regulatory authorities for all of our drugs in clinical development. If we, any of our CROs, third- party vendors, or clinical investigators fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, NMPA, TGA, Health Canada, EMA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with products produced under GMP. Our failure, or the failure of any third party, to comply with these regulations may result in our having to repeat clinical trials, which would delay the regulatory approval process. If any of our relationships with these third parties terminates, we may not be able to enter into arrangements with alternative CROs, vendors or clinical investigators, or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and other programs. If CROs 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 or our clinical investigators obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and any commercial prospects for our drugs would be harmed, our costs would increase and our ability to generate revenues would be delayed. Switching or adding additional CROs or clinical investigators involves additional cost and delays, which can materially affect our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter these delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition, results of operations, and prospects. Our ability to generate future revenues is dependent on our ability to work effectively with collaborators to develop our drug candidates, including to obtain regulatory approval. Our arrangements with collaborators will be critical to successfully bringing products to market and commercializing them, if approved. We rely on collaborators in various respects, including to undertake research and development programs, to conduct clinical trials, to manage or assist with the regulatory filings and approval process, and to assist with our commercialization efforts. We do not control our collaborators and we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If they fail to complete the remaining studies successfully, or at all, it would delay, adversely affect or prevent regulatory approval. We cannot guarantee the satisfactory performance of any of our collaborators' obligations and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the drug candidates which could materially and adversely affect our business, financial condition, results of operations, and prospects. We are also unable to predict how changing global economic or political conditions ~~, such as the ongoing conflicts between Ukraine and Russia and Israel and Palestine and related global economic sanctions,~~ or potential global health concerns, such as future health epidemics or pandemics, may impact our CROs, clinical investigators, third- party vendors, and other collaborators. Any negative impact could have a material adverse effect on our business, financial condition, results of operations, and prospects. We have entered into research collaborations and may form or seek collaborations, joint ventures or strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances, or licensing arrangements. We may form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur non- recurring and other costs, increase our near and long- term expenditures, disrupt our management and business, or issue securities that dilute our existing stockholders. While we have entered into collaborative research arrangements with some of the world' s leading academic institutions and research centers and are working with key

scientists in the field of central nervous system disorders, we face significant competition in seeking appropriate strategic partners and the negotiation process is time- consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug 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 drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, if approved, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. For any drug candidates that we may seek to in- license from third parties, we may face significant competition from other pharmaceutical or biotechnology companies with greater resources or capabilities than we have, and any agreement that we do enter into may not result in the anticipated benefits. Further, collaborations involving our drug candidates 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; ● collaborators may not pursue development and commercialization of our drug candidates, if approved, or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors outside of our control, such as a business combination that diverts resources or creates competing priorities; ● collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing; ● collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drugs; ● collaborators with marketing and distribution rights to one or more drugs may not commit sufficient resources to their marketing and distribution; ● collaborators may not properly develop, 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 drug candidates, if approved, or that result in costly litigation or arbitration that diverts management attention and resources; ● collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of our drug candidates, if approved; and ● collaborators may own or co- own intellectual property covering our drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property. As a result, we may not be able to realize the benefit of any current or future research collaborations, strategic partnerships, or the potential licensing of third- party drugs if we are unable to successfully integrate such products 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 net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of one of more of our drug candidates, reduce or delay our development program or one or more of our future development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or, if approved, bring them to market and generate product sales revenue, which would harm our business, financial condition, results of operations, and prospects. Our business depends on the use of raw materials, and a decrease in the supply or an increase in the cost of these raw materials or any quality issues in such raw materials could materially and adversely affect our business, financial condition, results of operations, and prospects. In order to manufacture our products, we must obtain sufficient quantities of high- quality raw materials at commercially acceptable prices and in a timely manner. Certain critical raw materials, such as wires made of high- purity gold and other transition elements, are available from a limited number of suppliers in the market. As a result, any disruption in production or inability of our suppliers to produce adequate quantities to meet our needs could impair our ability to operate our business on a day- to- day basis and to continue our research and development of future drug candidates. Moreover, we expect our demand for such materials to increase as we expand our business scale and commercialize our products, if approved, and we cannot guarantee that current suppliers have the capacity to meet our demand. We are also exposed to the risk of increased material costs, which we may not be able to pass on to customers and as a result, we could have lower profitability. In addition, although we have implemented quality inspection procedures on such materials before they are used in our manufacturing processes and also require our suppliers to maintain high quality standards, we cannot guarantee that we will be able to secure sufficient quantities of raw materials at high quality standards, nor detect all quality issues in the supplies we use. For example, should the highly purified water that we utilize be compromised in any way, it could render entire batches unusable or, depending on the nature of the impurity, could be dangerous to patients. Further, we cannot assure you that third parties will be able to maintain and renew all licenses, permits, and approvals necessary for their operations or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which in turn may result in shortages of the raw materials utilized by us. If we are unable to obtain adequate raw materials and the quality of our products suffers as a result, we may have to delay clinical trials and regulatory filings, recall our products, be subject to product liability claims, fail to comply with continuing regulatory requirements, and incur significant costs to rectify such issues, which may have a material and adverse effect on our business, financial condition, results of operations, and prospects. If we are unable to obtain and maintain sufficient patent protection for our drug candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products similar or identical to our products, and our ability to commercialize our

approved drugs successfully may be adversely affected. Our success depends in large part on our ability to protect our proprietary technology, drug candidates in clinical trials, and approved drugs on market (if approved) from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the drug candidates and technology that we consider commercially important by filing patent applications in most important commercial markets, including the U. S., China, Europe, Canada, Japan, Korea, and other countries, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. However, the patent prosecution process is expensive, time- consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. As a result, we may not be able to prevent competitors from developing and commercializing competitive drugs in all such fields and territories. Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and any other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U. S. and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions. Furthermore, China, EPO, and the U. S. have adopted the " first- to- file " system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first- to- file system, third parties may be granted a patent relating to a technology which we invented. The coverage sought by the claims in a patent application can be significantly reduced before the patent is issued, and the scope of the claims can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. The issuance of a patent is not conclusive as to our inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in any country. We may be subject to a third-party preissuance submission of prior art to the U. S. Patent and Trademark Office (" USPTO "), or become involved in opposition, derivation, revocation, re- examination, post- grant and inter partes review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or approved drugs and compete directly with us without payment, or result in our inability to manufacture or commercialize drug candidates and approved drugs without infringing, misappropriating or otherwise violating third- party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post- grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, 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 drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technology or drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non- infringing manner. Furthermore, although various extensions may be available, the life of a patent and the protection it affords, are limited. For example, approved therapies may face competition from generic medications after the related patents have expired, or if they are challenged and invalidated even before their expiry. Manufacturers of generic drugs may challenge the scope, validity or enforceability of our patents in court, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. The issued patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates as described in " Business — Intellectual Property " of this Annual Report. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drugs are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our products. Moreover, some of our patents and patent applications may in the future 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. Any of the foregoing could have a material adverse effect on our competitive position,

business, financial conditions, results of operations, and prospects. Intellectual property discovered through government funded programs may be subject to federal regulations such as " march- in " rights, certain reporting requirements and a preference for U. S.- based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non- U. S. manufacturers. Although we do not currently own issued patents or pending patent applications that have been generated through the use of U. S. government funding, we may acquire or license in the future intellectual property rights that have been generated through the use of U. S. government funding or grants. Pursuant to the Bayh- Dole Act of 1980, the U. S. government may have certain rights in inventions developed with government funding. These U. S. government rights include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as " march- in rights "). Such " march- in " rights can apply to new subject matter arising from the use of such government funding or grants and should not extend to pre- existing subject matter or subject matter arising from funds unrelated to the government funding or grants If the U. S. government exercised its march- in rights in our future intellectual property rights that are generated through the use of U. S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U. S. government for the exercise of such rights. The U. S. government also has the right to take title to these inventions if we fail to disclose the invention to the government or fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U. S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U. S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. industry may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. We may not be able to protect our intellectual property rights throughout the world or prevent unfair competition by third parties. Filing, prosecuting, maintaining, and defending patents on drug candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some non- U. S. countries can have a different scope and strength than do those in the U. S. In addition, the laws of certain non- U. S. countries do not protect intellectual property rights to the same extent as the laws of the U. S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S., or from selling or importing drugs made using our inventions in and into the U. S. or non- U. S. jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to non- U. S. jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in the U. S. These drugs may compete with our future approved drugs and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing. Geo-political actions in the U. S. and in foreign countries could also increase the uncertainties and costs surrounding the prosecution, maintenance, and defense of our patents. For example, the U. S. and foreign government actions related to Russia' s invasion of Ukraine may limit or prevent prosecution, maintenance, and defense of patents in Russia. These actions could result in abandonment or lapse of our patents, resulting in partial or complete loss of patent rights in Russia. 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 that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit- making activities in the United States and other countries that Russia has deemed unfriendly 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 drugs 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. We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. Our patent rights relating to our drugs could be found invalid or unenforceable if challenged in court or before the U. S. Patent and Trademark Office or comparable non- U. S. authority. Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, protect our trade secrets or determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Enforcement or defense of intellectual property rights can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and / or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation proceeding could put our patents, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. 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 patent litigation in the U. S., defendant counterclaims in district courts or in the Patent Trademark and Appeal Board alleging invalidity or unenforceability are

commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U. S. or abroad, even outside the context of litigation. Such mechanisms include ex parte re- examination, inter partes review, post- grant review, derivation and equivalent proceedings in non- U. S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. 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 drug candidates. Such a loss of patent protection could have a material adverse impact on our business. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U. S. 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. If we are sued for infringing the intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our drug candidates. Our commercial success depends in part on our avoiding infringement of the patents and other intellectual property rights of third parties. We are aware of other issued patents belonging to third parties that exist in fields in which we are developing our drug candidates. There may also be third- party patents or patent applications of which we are currently unaware, and given the dynamic area in which we operate, additional patents are likely to be issued that relate to some aspects of our business. There is a substantial amount of litigation and other claims and proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others. Third parties may assert that we are using technology in violation of their patent or other proprietary rights. Defense of these claims, regardless of their merit, could involve substantial litigation expense and divert our technical personnel, management personnel, or both from their normal responsibilities. If third parties bring successful claims against us for infringement of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our drug candidates. We may also have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, or redesign our infringing drug candidates, which may be impossible or require substantial time and cost. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our drug candidates. Any such license might not be available on reasonable terms or at all. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business. Intellectual property litigation may lead to unfavorable publicity that harms our reputation and increases our operating losses, causing the market price of our Common Stock to decline. During the course of any intellectual property litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our Common Stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to 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. 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. 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 noncompliance with these requirements. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and most foreign jurisdictions either annually or in several stages over the lifetime of the patent. The USPTO and various non- U. S. 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 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. If we do not obtain patent term extension and data exclusivity for any drug candidates we may develop, our business may be materially harmed. Depending upon the timing, duration, and specifics of any FDA marketing approval of any drug candidates we may develop, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch Waxman Amendments. The Hatch Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during clinical trials and the FDA regulatory review process. A comparable extension right may exist in other foreign jurisdictions as well. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to

exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, no patent term extension system has been established in China beyond the new pilot program, and implementation of the pilot program may not occur quickly. As a result, the patents we have in China are not yet eligible to be extended for patent term lost during clinical trials and the regulatory review process. If we are unable to obtain patent term extension or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed. Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates. The U. S. has recently enacted and is currently implementing wide- ranging patent reform legislation. 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, if any. Depending on decisions by the U. S. Congress, the federal courts and the USPTO, 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. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or other intellectual property rights. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to our issued patents and pending patent applications, we rely on trade secrets, including unpatented know- how, technology, and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach such agreements and disclose our proprietary information, 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 can be difficult, expensive, time- consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent the competitor from using that technology or information to compete with us and our competitive position would be harmed. We may be subject to claims that our employees have wrongfully used or disclosed the alleged trade secrets of their former employers. Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non- disclosure and non- competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantages. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative: ● others may be able to make compounds that are similar to our drug candidates but that are not covered by the claims of the patents that we own or may in the future exclusively license; ● we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future exclusively license, which could result in the patent applications not issuing or being invalidated after issuing; ● we might not have been the first to file patent applications covering certain of our inventions, which could prevent the issuance of the patent applications or cause them to be invalidated after issuance; ● 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 not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; ● we may obtain patents for certain drug candidates many years before we receive NDA approval for these drugs, and because patents have a limited life, which may begin to run prior to the commercial sale of the related drugs, limiting the commercial value of our patents; ● 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 drugs for commercialization in our major markets; ● we may fail to develop additional proprietary technologies that are patentable; ● we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; ● the patents of others may have an adverse effect on our business, for example by preventing us from commercializing one or more of our drug candidates for one or more indications; and ● any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business. Risks Related to the Reverse Recapitalization and Integration of Businesses We have incurred significant increased expenses and administrative burdens as a public company, which could have an adverse effect on our business, financial condition and results of operations. As a public company, and particularly after we are no longer a smaller reporting company, we have faced and will continue to face increased legal, accounting, administrative and other costs and expenses as a public company that we did not incur as a private company. The Sarbanes- Oxley Act, including the requirements of Section 404, as well as rules and

regulations subsequently implemented by the U. S. Securities and Exchange Commission (" SEC "), the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations promulgated and to be promulgated thereunder, the Public Company Accounting Oversight Board and the securities exchanges, impose additional reporting and other obligations on public companies. Compliance with public company requirements has increased costs and made certain activities more time- consuming. A number of those requirements ~~has~~ **have** required us to carry out activities we have not done previously. Our management and other personnel also have devoted and will continue to devote a substantial amount of time to these compliance initiatives. In addition, additional expenses associated with SEC reporting requirements have been incurred. Furthermore, if any issues in complying with those requirements are identified (for example, if the auditors identify a material weakness or significant deficiency in the internal control over financial reporting), we could incur additional costs rectifying those issues, and the existence of those issues could adversely affect our reputation or investor perceptions of it. It is also more expensive to obtain director and officer liability insurance. Risks associated with our status as a public company may make it more difficult to attract and retain qualified persons to serve on the board of directors or as executive officers. The additional reporting and other obligations imposed by these rules and regulations has increased legal and financial compliance costs and the costs of related legal, accounting and administrative activities. These increased costs require us to divert a significant amount of money that could otherwise be used to expand our business and achieve strategic objectives. Advocacy efforts by stockholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs. We qualify as a smaller reporting company within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to smaller reporting companies, it could make our Common Stock less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies. We are a " smaller reporting company " because the market value of our stock held by non- affiliates was less than $ 250 million as of June 30, ~~2023~~ **2024** . We may continue to be a smaller reporting company in any given year if either (i) the market value of our stock held by non- affiliates is less than $ 250 million as of June 30 in the most recently completed fiscal year or (ii) our annual revenue is less than $ 100 million during the most recently completed fiscal year and the market value of our stock held by non- affiliates is less than $ 700 million as of June 30 in the most recently completed fiscal year. As a smaller reporting company, we are eligible for and may take advantage of certain exemptions from various reporting requirements applicable to other public companies for as long as we continue to be a smaller reporting company, including: (i) the choice of presenting only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10- K, (ii) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404 (b) of the Sarbanes- Oxley Act, and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our Common Stock less attractive because we rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile. Risks Related to Our Common Stock Provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our Common Stock. Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares of our Common Stock. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock, thereby depressing the market price of our Common Stock. Such provisions include the following: ● a classified board of directors with three- year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our Board; ● the ability of our Board to approve the issuance shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror and / or existing stockholders; ● the requirement for the affirmative vote of holders of at least 66⅔ % of the voting power of all of the then- outstanding shares of the Common Stock, voting together as a single class, to amend certain provisions of our amended and restated certificate of incorporation or our amended and restated bylaws, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt; ● the exclusive right of our Board to elect a director to fill a vacancy created by the expansion of our Board or the resignation, retirement death, disqualification or removal of a director, which prevents stockholders from being able to fill vacancies on our Board for a period of time; and ● the requirement that a special meeting of stockholders may be called only by our Board, the chairman of our Board or our **CEO** ~~Chief Executive Officer~~ , which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors. These and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our Board or initiate actions that are opposed by our then- current Board, including the ability to delay or impede a merger, tender offer or proxy contest. The existence of these provisions could negatively affect the price of our Common Stock and limit opportunities for stockholders to realize value in a corporate transaction. Future offerings of debt or equity securities by us may adversely affect the market price of our Common Stock. In the future, we may attempt to obtain financing or to further increase our capital resources by issuing additional shares of our Common Stock or offering debt or other equity securities, including commercial paper, medium- term notes, senior or subordinated notes, debt securities convertible into equity or shares of preferred stock. Future clinical trials, commercialization efforts, and acquisitions could require substantial additional capital in excess of cash from operations. We would expect to obtain the capital required for acquisitions through a combination of additional issuances of equity, corporate indebtedness and / or cash from operations. Issuing additional shares of our Common Stock or other equity securities or securities convertible into equity may dilute the economic and voting rights of our existing stockholders or reduce the market price of our Common Stock or both. Upon liquidation, holders of such debt securities and preferred shares, if issued,

and lenders with respect to other borrowings would receive a distribution of our available assets prior to the holders of our Common Stock. Debt securities convertible into equity could be subject to adjustments in the conversion ratio pursuant to which certain events may increase the number of equity securities issuable upon conversion. Preferred shares, if issued, could have a preference with respect to liquidating distributions or a preference with respect to dividend payments that could limit our ability to pay dividends to the holders of our Common Stock. Our decision to issue securities in any future offering will depend on market conditions and other factors beyond our control, which may adversely affect the amount, timing and nature of our future offerings. General Risk Factors ~~We do not satisfy all continued listing requirements of Nasdaq.~~ There can be no assurance that we will be able to comply with the continued listing requirements of Nasdaq. ~~As previously disclosed, on August 1, 2023, we received a written notice from Nasdaq that for the last 30 consecutive business days, the bid price for our Common Stock had closed below the minimum $ 1. 00 per share requirement for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5550 (a) (2) (the " Minimum Bid Price Requirement "). In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), the Company had a period of 180 calendar days, or until January 29, 2024, to regain compliance with the Minimum Bid Price Requirement. On January 30, 2024, the Company received a notice from Nasdaq that, while the Company has not regained compliance with the Minimum Bid Price Requirement, in accordance with Nasdaq Listing Rule 5810 (c) (3) (A), it is eligible for an additional 180 calendar day period, or until July 29, 2024, to regain compliance with the Minimum Bid Price Requirement (the " January Notice "). The January Notice has no immediate effect on the listing of our Common Stock and our Common Stock will continue to be listed on Nasdaq under the symbol " CLNN. " Nasdaq' s determination to grant us an additional 180 calendar day period to regain compliance is based on us meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on Nasdaq, with the exception of the Minimum Bid Price Requirement, and on our written notice to Nasdaq on January 16, 2024 of our intention to cure the deficiency during the additional 180- day compliance period, including by effecting a reverse stock split, if necessary. If at any time during this additional 180- day compliance period, the bid price of our Common Stock closes at $ 1. 00 per share or more for a minimum of 10 consecutive business days, Nasdaq will provide us with a written confirmation of compliance with the Minimum Bid Price Requirement. If we do not regain compliance with the Minimum Bid Price Requirement by July 29, 2024, Nasdaq will provide us written notification that our Common Stock will be delisted. At that time, we may appeal the delisting determination to a Nasdaq hearings panel. We intend to actively monitor the bid price for our Common Stock between now and July 29, 2024, and will consider our available options to regain compliance with the Minimum Bid Price Requirement.~~ There can be no assurance that we will **be able to** ~~regain compliance with the Minimum Bid Price Requirement or~~ maintain compliance with any of the ~~other~~ Nasdaq continued listing requirements. If Nasdaq delists our shares of Common Stock or warrants from trading on its exchange for failure to meet Nasdaq' s listing requirements, we and our stockholders could face significant material adverse consequences including: ● a limited availability of market quotations for our securities; ● reduced liquidity for our securities; ● a determination that our Common Stock is a " penny stock " which will require brokers trading in our Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities; ● a limited amount of news and analyst coverage; and ● a decreased ability to issue additional securities or obtain additional financing in the future. The price of our Common Stock may be volatile. The stock markets in general and the markets for biotechnology stocks have experienced extreme volatility. The market for the common stock of smaller companies such as ours is characterized by significant price volatility when compared to the shares of larger, more established companies that trade on a national securities exchange and have large public floats, and the share price of our Common Stock is more volatile than the price of the shares of such larger, more established companies and will continue to be for the indefinite future. The price of our Common Stock may fluctuate due to a variety of factors, including: ● changes in the industries in which we operate; ● variations in our operating performance and the performance of our competitors in general; ● material and adverse impact of health epidemics or pandemics on the markets and the broader global economy; ● actual or anticipated fluctuations in our quarterly or annual operating results; ● publication of research reports by securities analysts about us or our competitors or our industry; ● the public' s reaction to our press releases, our other public announcements and our filings with the SEC; ● our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market; ● additions and departures of key personnel; ● changes in laws and regulations affecting our business; ● commencement of, or involvement in, litigation involving us; ● changes in our capital structure, such as future issuances of securities or the incurrence of additional debt; ● the volume of shares of our Common Stock available for public sale; and ● general economic, political, industry, and market conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks, epidemics and pandemics, and acts of terrorism or war ~~(such as the ongoing conflicts between Ukraine and Russia and Israel and Palestine)~~. These market and industry factors may materially reduce the market price of our Common Stock regardless of our operating performance. SEC regulations limit the amount of funds we can raise during any 12- month period pursuant to our shelf registration statement on Form S- 3. SEC regulations limit the amount that companies with a public float of less than $ 75 million may raise during any 12- month period pursuant to a shelf registration statement on Form S- 3. Under General Instruction I. B. 6 to Form S- 3 (the " Baby Shelf Rule "), the amount of funds a company can raise through primary public offerings of securities in any 12- month period using a registration statement on Form S- 3 pursuant to the Baby Shelf Rule is limited to one- third of the aggregate market value of its shares of common stock held by non- affiliates of the company. Currently, we are constrained by the Baby Shelf Rule. Even if sufficient funding is available, there can be no assurance that it will be available on terms acceptable to us or our stockholders. Furthermore, if we are required or choose to file a new registration statement on a form other than Form S- 3, we may incur additional costs and be subject to delays due to review by the SEC staff.