

Risk Factors Comparison 2025-02-26 to 2024-02-21 Form: 10-K

Legend: New Text Removed Text Unchanged Text Moved Text Section

We are presently dependent largely upon the experience, abilities and continued services of Jeffrey Frelick, our President and Chief Executive Officer, and Deina Walsh, our Chief Financial Officer. The loss of services of Mr. Frelick or Ms. Walsh could have a material adverse effect on our business, financial condition or results of operations. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other biotechnology companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives. Competitors could develop and / or gain FDA approval of our products for a different indication. Another company may obtain FDA approval for similar products that might adversely affect our ability to develop and market our product candidates in the U. S. We are aware that other companies have intellectual property protection and have conducted clinical trials. Many of these companies may have more resources than us. We cannot provide any assurances that our product candidates will be FDA- approved prior to our competitors. The FDA does not regulate the practice of medicine and, as a result, cannot direct physicians to select certain products for their patients. Consequently, we might be limited in our ability to prevent off- label use of a competitor' s product to treat the diseases we intend our product candidates to address, even if we have issued method of use patents for that indication. If we are not able to obtain and enforce our patents, a competitor could develop and commercialize similar products for the same indications that we are pursuing. We cannot provide any assurances that a competitor will not obtain FDA approval for a product that contains the same active ingredients as our products. We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. We face competition from numerous medical device, pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions for our current product candidate or future product candidates. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. Competition could result in reduced sales and pricing pressure on our current product candidate or future product candidates, if approved, which in turn would reduce our ability to generate meaningful revenues and have a negative impact on our results of operations. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidates. The biotechnology industry is intensely competitive and involves a high degree of risk. We compete with other companies that have far greater experience and financial, research and technical resources than us. Potential competitors in the U. S. and worldwide are numerous and include medical device, pharmaceutical and biotechnology companies, educational institutions and research foundations, many of which have substantially greater capital resources, marketing experience, research and development staffs and facilities than ours. Some of our competitors may develop and commercialize products that compete directly with those incorporating our technology or may introduce products to market earlier than our product candidates or on a more cost- effective basis. Our competitors compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our technology. We may face competition with respect to product efficacy and safety, ease of use and adaptability to various modes of administration, acceptance by physicians, the timing and scope of regulatory approvals, availability of resources, reimbursement coverage, price and patent position, including the potentially dominant patent positions of others. An inability to successfully complete our product development or commercializing our product candidates could result in our having limited prospects for establishing market share or generating revenue. Many of our competitors or potential competitors have significantly greater established presence in the market, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do, and as a result may have a competitive advantage over us. Mergers and acquisitions in the medical device, pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These 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 and technology licenses complementary to our programs or potentially advantageous to our business. As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to obtain patent protection or other intellectual property rights, which will limit our ability to develop or commercialize our current product candidate or future product candidates. Our competitors may also develop devices that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or non- competitive before we can recover the expenses of development and commercialization. The impact of public health crises is difficult to predict and could materially and adversely affect our

business and results of operations. Any adverse widespread public health developments in locations where we conduct business, as well as any governmental restrictive measures implemented to control such outbreaks and consumer responses to such outbreaks, could have a material adverse impact on our business and results of operations. For instance, our clinical trials may be affected by a public health crisis. Site initiation, participant recruitment and enrollment, and study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward the public health crisis efforts, or other reasons related to the public health crisis. During a public health crisis, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Further, if our operations are adversely impacted by a public health crisis, we risk a delay, default and / or non- performance under existing agreements which may increase our costs. These cost increases may not be fully recoverable or adequately covered by insurance. Additionally, infections and deaths related to a public health crisis may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA review and / or approval with respect to, our clinical trials. We cannot predict how long these disruptions could continue, were they to occur. Any elongation or de- prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates. Furthermore, we currently utilize third parties to, among other things, manufacture raw materials. Third- parties in the supply chain for materials used in the production of our product candidates may be adversely impacted by restrictions resulting from public health crises which could limit our ability to manufacture our product candidates for our clinical trials and research and development operations. These impacts could be significant and long term. Further, any actions taken to mitigate any health crises could lead to an economic recession. For example, the COVID- 19 pandemic and the efforts to control it caused significantly increased economic uncertainty, global inflationary pressure, supply chain disruptions, volatility in the capital markets, significant economic deterioration, and an increasingly competitive labor market. The ultimate impact of a public health crisis on our business operations will depend on, among other things, the severity and length of the health crisis, the duration, effectiveness and extent of the mitigation measures and actions designed to contain the outbreak, the emergence, contagiousness and threat of new and different strains of the disease, the availability and efficacy of vaccines and effective treatments, public acceptance of vaccines and treatments for the disease, if any, as well as the resulting economic conditions and how quickly and to what extent normal economic and operating conditions resume, all of which are highly uncertain. Such extraordinary events and their aftermaths can cause investor fear and panic, which could further materially and adversely affect our operations, the economies in which we operate, and the financial markets generally in ways that cannot necessarily be predicted and which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from a public health crisis could materially and adversely affect our business and the value of our common stock. Significant disruptions of information technology systems, computer system failures or breaches of information security could adversely affect our business. We rely and plan to rely to a large extent upon sophisticated information technology systems to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property). The size and complexity of our information technology and information security systems, and those of our third- party vendors with whom we may contract, make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever- increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we intend to invest in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Our internal computer systems, and those of our CROs, our CDMOs, and other business vendors on which we may rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs. Any interruption or breach in our systems could adversely affect our business operations or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they use to trade in our securities. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our current and future product candidates could be delayed and our business could be otherwise adversely affected. We will need to grow the size of our organization in the future, and we may experience difficulties in managing this growth. As of the date of this filing, we had two full- time employees. We will need to grow the size of our organization in order to support our continued development and potential commercialization of our product candidate. As our development and commercialization plans and strategies continue to develop, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources may increase. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including: ● managing our clinical trials effectively; ● identifying, recruiting, maintaining, motivating and integrating additional employees; ● managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties; ● improving our managerial, development, operational, information technology, and finance systems; and ● expanding our facilities. If our operations expand, we will also need to manage additional

relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidate and to compete effectively will depend, in part, on our ability to manage any future growth effectively, as well as our ability to develop a sales and marketing force when appropriate for our company. To that end, we must be able to manage our development efforts and preclinical studies and clinical trials effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. The failure to accomplish any of these tasks could prevent us from successfully growing our company. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our current product candidate or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our product. If we cannot successfully defend ourselves against claims that our product candidate or product caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidates or products that we may develop; • termination of clinical trial sites or entire clinical trial programs; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • significant costs to defend the related litigation; • substantial monetary awards to trial subjects or patients; • loss of revenue; • diversion of management and scientific resources from our business operations; and • the inability to commercialize any products that we may develop. Prior to engaging in our first-in-man pilot clinical study in Australia, we obtained product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks. Prior to engaging in future clinical trials, we intend to obtain product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks; however, we may be unable to obtain such coverage at a reasonable cost, if at all. If we are able to obtain product liability insurance, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise and such insurance may not be adequate to cover all liabilities that we may incur. Furthermore, we intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidate in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on devices that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business. Our ability to use net operating losses to offset future taxable income may be subject to limitations. As of December 31, 2023-2024, we had federal net operating loss, or NOLs, carryforwards of approximately \$ 30-34, 987-585, 000. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 years under applicable U. S. tax laws, and will begin to expire, if not utilized, beginning in 2027-2037. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, federal NOLs incurred in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the Tax Act, or whether any further regulatory changes may be adopted in the future that could minimize its applicability. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and certain 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 the ownership of its equity 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 may be limited.

Risks Related to Healthcare Compliance Regulations Our relationships with customers and third- party payors will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. If we or they are unable to comply with these provisions, we may become subject to civil and criminal investigations and proceedings that could have a material adverse effect on our business, financial condition and prospects. Healthcare providers, physicians and third- party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our current and future arrangements with healthcare providers, healthcare entities, third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, develop and will market, sell and distribute our product. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients’ rights are applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following: • the federal healthcare Anti- Kickback Statute which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; • federal civil and criminal false claims laws, including the federal False Claims Act that can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws, prohibit individuals or entities from knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any

materially false statements in connection with the delivery of or payment for healthcare benefits, items or services, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 which imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information; ● the federal physician sunshine requirements under the ACA which requires certain manufacturers of, devices, biologics and medical supplies, with certain exceptions, to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; ● analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or pricing information; and certain state and local laws which require the registration of pharmaceutical sales representatives; and ● state and foreign laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. The application of privacy provisions of HIPAA is uncertain. The application of privacy provisions of HIPAA is uncertain. HIPAA, among other things, protects the privacy and security of individually identifiable health information by limiting its use and disclosure. HIPAA directly regulates "covered entities" (healthcare providers, insurers and clearinghouses) and indirectly regulates "business associates" with respect to the privacy of patients' medical information. All entities that receive and process protected health information are required to adopt certain procedures to safeguard the security of that information. It is uncertain whether we would be deemed to be a covered entity under HIPAA, and it is unlikely that we, based on our current business model, would be a business associate. Nevertheless, we may be contractually required to physically safeguard the integrity and security of any patient information that we receive, store, create or transmit. If we fail to adhere to our contractual commitments, then certain of our contract counterparties may be subject to civil monetary penalties and this could adversely affect our ability to market our product. If we are deemed to be a vendor, under the Health Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment Act of 2009, then we will be obligated to adopt various security measures. We may also be subject to state and foreign privacy laws under which breaches could lead to substantial fines and liability.

Risks Related to Owning our Common Stock The price of our common stock and public warrants may fluctuate substantially. You should consider an investment in our common stock to be risky. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section are: ● our ability to meet the Nasdaq listing requirements; ● volatility and limitations in trading volumes of our shares of common stock; ● our ability to obtain financing to conduct and complete research and development activities including, but not limited to, our clinical trials, and other business activities; ● the timing and success of our clinical trials and introduction of products to the market; ● changes in the development status of our product candidate; ● any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned preclinical and clinical trials; ● safety concerns related to the use of our product candidate; ● changes in our capital structure or dividend policy, future issuances of securities, sales of large blocks of common stock by our stockholders; ● our cash position; ● announcements and events surrounding financing efforts, including debt and equity securities; ● changes in general economic, political and market conditions in or any of the regions in which we conduct our business; ● analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage; ● departures and additions of key personnel; ● disputes and litigation; ● changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and ● other events or factors, many of which may be out of our control. In addition, if the market for stock in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management. Future sales and issuances of our common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall. We expect that significant additional capital will be needed in the future to continue our planned operations, including increased marketing, hiring new personnel, commercializing our product, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we

sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. Moreover, the perceived risk of this potential dilution could cause stockholders to attempt to sell their shares and investors to short our common stock. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, and may cause you to lose the value of your investment. There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq, a failure of which could result in a delisting of our common stock and certain warrants. Nasdaq requires that the trading price of listed stock remain above \$ 1.00 in order for the stock to remain listed. If a listed stock trades below \$ 1.00 for more than 30 consecutive trading days, then it is subject to delisting from the Nasdaq. In addition, to maintain a listing on Nasdaq, we must satisfy minimum financial and other continued listing standards, including those regarding minimum stockholders' equity, minimum publicly available shares, director independence and independent committee requirements and other corporate governance requirements. We recently regained compliance with Nasdaq's listing standards, and Nasdaq will continue to monitor our compliance with its requirements ~~including through a Nasdaq discretionary panel monitor until June 28, 2024~~. If we are unable to satisfy these standards, we could be subject to delisting, which would have a negative effect on the price of our common stock, impair your ability to sell or purchase our common stock or warrants when you wish to do so, and potentially cause you to lose the value of your investment in us. In the event of a delisting, we would expect to take actions to restore our compliance with the listing standards, but we can provide no assurance that any action we take to restore our compliance would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the minimum bid price requirement, or prevent future noncompliance with the listing requirements. If the Company is delisted from Nasdaq, its common stock may be eligible for trading on an over-the-counter market. If the Company is not able to obtain a listing on another stock exchange or quotation service for its common stock, it may be extremely difficult or impossible for stockholders to sell their shares of common stock. Moreover, if the Company is delisted from Nasdaq, but obtains a substitute listing for its common stock, it will likely be on a market with less liquidity, and therefore experience potentially more price volatility than experienced on Nasdaq. Stockholders may not be able to sell their shares of common stock on any such substitute market in the quantities, at the times, or at the prices that could potentially be available on a more liquid trading market. As a result of these factors, if the Company's common stock is delisted from Nasdaq, the value and liquidity of the Company's common stock would likely be significantly adversely affected. A delisting of the Company's common stock from Nasdaq could also adversely affect the Company's ability to obtain financing for its operations and / or result in a loss of confidence by investors, employees and / or business partners. We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the increase, if any, of our share price. The right of our President and Chief Executive Officer and Chief Financial Officer to participate in future financings of ours could impair our ability to raise capital. Jeffrey Frelick, our President and Chief Executive Officer, and Deina Walsh, our Chief Financial Officer, hold contractual preemptive rights which allow them to participate, at their option, in all future financings up to an amount necessary to maintain their percentage interest in our common stock. The existence of such preemptive rights, or the exercise of such rights, may deter potential investors from providing us needed financing, or may deter investment banks from working with us. This may have a material adverse effect on our ability to raise capital which, in turn, could have a material adverse effect on our business prospects. If our shares of common stock become subject to the penny stock rules, it would become more difficult to trade our shares. The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than \$ 5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on Nasdaq and if the price of our common stock is less than \$ 5.00, our common stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares. General Risk Factors If we are unable to establish appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations, result in the restatement of our financial statements, harm our operating results, subject us to regulatory scrutiny and sanction, cause investors to lose confidence in our reported financial information and have a negative effect on the market price for shares of our common stock. Effective internal controls are necessary for us to provide reliable financial reports and to effectively prevent fraud. We maintain a system of internal control over financial reporting, which is defined as a process designed by, or under the supervision of, our principal executive officer and principal financial officer, or persons performing similar functions, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. As of December 31, ~~2023~~ **2024**, management assessed the effectiveness of our internal controls over financial reporting, and based on that evaluation, they concluded that our internal controls and procedures were effective. As a public company, we have significant additional requirements for enhanced

financial reporting and internal controls. We are required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes- Oxley Act of 2002, which requires annual management assessments of the effectiveness of our internal controls over financial reporting. The process of designing and implementing effective internal controls is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. We cannot assure you that we will not, in the future, identify areas requiring improvement in our internal control over financial reporting. We cannot assure you that the measures we will take to remediate any areas in need of improvement will be successful or that we will implement and maintain adequate controls over our financial processes and reporting in the future as we continue our growth. If we are unable to establish appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations, result in the restatement of our financial statements, harm our operating results, subject us to regulatory scrutiny and sanction, cause investors to lose confidence in our reported financial information and have a negative effect on the market price for shares of our common stock. We may be at risk of securities class action litigation. We may be at risk of securities class action litigation. In the past, medical device, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business and results in a decline in the market price of our common stock. Market and economic conditions may negatively impact our business, financial condition and share price. Concerns over public health crises, energy costs, terrorism and geopolitical issues, the U. S. mortgage market and a deteriorating real estate market, unstable global credit and financial markets and financial conditions, inflationary pressures and interest rate changes, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth, increased unemployment rates, and increased credit defaults in recent years. More recently, the closures of Silicon Valley Bank and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation (FDIC) created bank- specific and broader financial institution liquidity risk and concerns. Future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market- wide liquidity shortages, impair the ability of companies to access near- term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If these conditions or the equity markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short- term liquidity risk and also make any necessary 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 plans and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to conduct our business plans on schedule and on budget. If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, our stock price and trading volume may decline. The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers. Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws, and Delaware law may have anti- takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline. Our Certificate of Incorporation, Bylaws, and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 20, 000, 000 shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our Board of Directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management. Provisions of our Certificate of Incorporation and our Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, the certificate of incorporation and bylaws and Delaware law, as applicable, among other things: • provide the Board of Directors with the ability to alter the Bylaws without stockholder approval; • place limitations on the removal of directors; • establishing advance notice requirements for nominations for election to the Board of Directors or for proposing matters that can be acted upon at stockholder meetings; and • provide that vacancies on the Board of Directors may be filled by a majority of directors in office, although less than a quorum. Provisions of our warrants could discourage an acquisition of us by a third party. In addition to the

discussion of the provisions of our certificate of incorporation and our bylaws, certain provisions of our warrants could make it more difficult or expensive for a third party to acquire us. The warrants prohibit us from engaging in certain transactions constituting “ fundamental transactions ” unless, among other things, the surviving entity assumes our obligations under the warrants. These and other provisions of the warrants could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you. Financial reporting obligations of being a public company in the U. S. are expensive and time- consuming, and our management will be required to devote substantial time to compliance matters. As a publicly traded company we incur significant additional legal, accounting and other expenses. The obligations of being a public company in the U. S. require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the **Securities Exchange Act of 1934, as amended (the “ Exchange Act ”)**, and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the Jumpstart Our Business Startups Act, and the listing requirements of the stock exchange on which our securities are listed. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. These reporting requirements, rules, and regulations will make some activities more time- consuming and costly and may make it more difficult and more expensive for us to maintain director and officer liability insurance. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems. Item 1B. Unresolved Staff Comments