

Risk Factors Comparison 2025-02-24 to 2024-03-15 Form: 10-K

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Investing in our common stock involves a high degree of risk. Before purchasing our common stock, you should read and consider carefully the following risk factors as well as all other information contained in this report, including our financial statements and the related notes. Each of these risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock. There may be additional risks that we do not presently know of or that we currently believe are immaterial, which could also impair our business and financial position. If any of the events described below were to occur, our financial condition, our ability to access capital resources, our results of operations and / or our future growth prospects could be materially and adversely affected and the market price of our common stock could decline. As a result, you could lose some or all of any investment you may make in our common stock.

Risks Relating to Our Business

We are an early-stage clinical biopharmaceutical company with limited operating history. We are an early-stage clinical biopharmaceutical company incorporated on January 2, 2014, and have limited operating history. We have not commenced revenue-producing operations apart from limited grant and service revenue. To date, our operations have consisted of the development of our proprietary microbial library, the identification, characterization, genetic engineering and testing of certain bacterial species to provide therapeutic effect and the development of our initial product candidates. Our limited operating history makes it difficult for potential investors to evaluate our technology or prospective operations. As an early-stage clinical biopharmaceutical company, we are subject to all the risks inherent in the organization, financing, expenditures, complications and delays involved with a new business. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially early-stage clinical-stage biopharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we may be unable to:

- successfully implement or execute our business plan, or that our business plan is sound;
- successfully complete preclinical and clinical trials and obtain regulatory approval for the marketing of our product candidates;
- successfully demonstrate a favorable differentiation between our precision dermatological product candidates and the current products on the market;
- successfully contract for the manufacture of our clinical drug products and establish a commercial drug supply;
- secure market exclusivity or adequate intellectual property protection for our product candidates;
- attract and retain an experienced management and advisory team; and
- raise sufficient funds in the capital markets to effectuate our business plan, including product and clinical development, regulatory approval and commercialization for our product candidates.

Investors should evaluate an investment in us in light of the uncertainties encountered by developing companies in a competitive environment. There can be no assurance that our efforts will be successful or that we will ultimately be able to attain profitability. If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be adversely affected. You must be prepared to lose all of your investment. We have a history of significant operating losses and anticipate continued operating losses for the foreseeable future. For the fiscal years ended December 31, 2024 and 2023, we incurred a net loss of \$ 9. 0 million and \$ 11. 3, respectively. As of December 31, 2024, we had an accumulated deficit of \$ 57. 6 million. We expect to continue to incur substantial expenses without any meaningful revenues unless and until we are able to obtain regulatory approval and successfully commercialize at least one of our product candidates. We also believe that, at a minimum, it will take us four to six years from the date of this report for us to obtain regulatory approval of our first drug candidates, assuming we are able to get regulatory approval at all. Even if we are able to commercialize our product candidates, there can be no assurance that we will generate significant revenues or ever achieve profitability. We expect to have significant research, regulatory and development expenses as we advance our product candidates towards commercialization. As a result, we expect to incur substantial losses for the foreseeable future, and these losses will be increasing. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable may impair our ability to sustain operations and adversely affect our business and our ability to raise capital. If we are unable to generate positive cash flow within a reasonable period of time, we will be unable to further pursue our business plan or continue operations, in which case you may lose your entire investment. The report of our independent registered public accounting firm for the year ended December 31, 2024 states that due to our accumulated deficit, recurring and negative cash flow from operations there is substantial doubt about our ability to continue as a going concern. We expect we will need additional financing to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all. As of December 31, 2024, we had total assets of \$ 7. 4 million and working capital of \$ 3. 9 million. In January, 2025, we completed a public offering of 4, 857, 780 shares of our common stock, at an offering price of \$ 0. 30 per share, in which we received net proceeds of approximately \$ 1. 3 million, after deducting underwriter discounts and offering expenses, and February 2025 we completed a registered direct offering of 2, 495, 518 shares of our common stock, at an offering price of \$ 0. 2785 per share, in which we received net proceeds of approximately \$ 695 thousand, after deducting placement agent commissions and offering expenses. After giving effect to both offerings, we believe that our cash on hand as of the date of this report will not be sufficient to cover our proposed plan of operations

beyond six months from the date of this report. We intend to seek additional funds through various financing sources, including the sale of our equity, licensing fees for our technology and joint ventures with industry partners. In addition, we will consider alternatives to our current business plan that may enable us to achieve revenue producing operations and meaningful commercial success with a smaller amount of capital. However, there can be no guarantees that such funds will be available on commercially reasonable terms, if at all. If such financing is not available on satisfactory terms, we may be unable required to scale back our proposed plan of operations and we may be unable to continue operations, in which case you may lose your entire investment. The clinical and commercial utility of our microbial library and genetic engineering platform is uncertain and may never be realized. We have built a proprietary platform that includes a microbial library comprised of approximately 1,500 unique bacterial strains that can be screened for unique therapeutic characteristics. The platform is augmented by artificial intelligence, machine learning and genetic engineering technologies. To date, our focus is on the development of genetically engineered strains of *S. epidermidis*, which we consider to be an optimal therapeutic candidate species for engineering of dermatologic therapies. However, we believe that the genetic engineering of *S. epidermidis* is a novel and unproven mode of therapy. We recently initiated our Phase 1b clinical trial for ATR-12 and dosed our first patient in August 2024 and expect to dose the first patient in the Phase 1 / 2 trial of ATR-04 in the first half of 2025. However, success in early clinical trials does not ensure that large-scale clinical trials will be successful, nor does it predict final results. Even after the completion of our proposed Phase 1b clinical trials, our initial product candidates will have only been tested in a small number of patients. Results from these clinical trials may not necessarily be indicative of the safety and tolerability or efficacy of our product candidates or our as we expand into larger clinical trials. Until such time, if ever, as we are able to provide the FDA with substantial clinical evidence to support a claim of safety, efficacy, purity and potency sufficient to enable the FDA to approve our proprietary product candidates for any indication, our proprietary microbial library and genetic engineering platform will remain unproven. Our product candidates are in early-stage clinical trials or early stages of preclinical development, and therefore they will require extensive additional preclinical and clinical testing. Success in preclinical studies or early-stage clinical trials may not be indicative of results in future clinical trials and we cannot assure you that any ongoing, planned or future clinical trials will lead to results sufficient for the necessary regulatory approvals. Because our product candidates are in early stages clinical trials or of preclinical development, they will require extensive preclinical and clinical testing. We dosed the first patient in our Phase 1b clinical trial for ATR-12 in August 2024, and we expect to dose the first patient in our Phase 1 / 2 clinical trial for ATR-04 in the first half of 2025. However, we have not conducted meaningful preclinical studies for any of our other product candidates. Success in preclinical testing and early-stage clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical studies and Phase 1b clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Phase 1b clinical trials also test how well a certain disease responds to a new treatment. Success in preclinical studies and earlier clinical trials does not ensure that later efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or even if they successfully advance through earlier clinical trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks, including failure in late-stage clinical trials even after achieving promising results in preclinical testing and earlier clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. Further, we cannot predict with any certainty if or when we might submit a Biologics License Application, or BLA, for regulatory approval for any of our product candidates or whether any such BLA will be accepted for review by the FDA, or whether any BLA will be approved upon review. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for their proposed uses. This failure could cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. We will need to grow the size of our organization, and we may experience difficulties in managing this growth. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee and consultant / contractor base. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize our product candidates and any other future product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage our future growth. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of our senior management would adversely impact our business prospects. Our management team has expertise in many different aspects of drug

development and commercialization. However, our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We will need to hire additional personnel as we further develop our product candidates. Competition for skilled personnel in our market is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. The loss of the services of any of our executive officers or other key employees, or our inability to hire targeted executives, could potentially harm our business, operating results or financial condition. In particular, we believe that the loss of the services of our chief executive officer would have a material adverse effect on our business. Other biopharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited. We currently have no sales and marketing organization. If we are unable to establish satisfactory sales and marketing capabilities or secure a third-party sales and marketing relationship, we may not be able to successfully commercialize any of our product candidates. At present, we have no sales or marketing personnel. Upon and subject to initial receipt of the requisite regulatory approvals for one or more of our drug products, we plan to build focused capabilities in the United States to commercialize our development programs focused on live biotherapeutic products and recombinant proteins for the treatment of skin diseases, where we believe the patient populations and medical specialists for the indications we are targeting are sufficiently concentrated to allow us to effectively promote our products with a targeted sales team. In other markets for which commercialization may be less capital efficient for us, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates. In some cases, we may pursue the licensing of our microbial library or patent rights or enter into a joint development arrangement. If we are not successful in recruiting sales and marketing personnel and building a sales and marketing infrastructure or entering into appropriate collaboration arrangements with third parties, we will have difficulty successfully commercializing our product candidates, which would adversely affect our business, operating results and financial condition. Even if we enter into third-party marketing and distribution arrangements, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. In terms of establishing a sales and marketing infrastructure, we will have to compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to build an internal sales organization or enter into collaboration arrangements with third parties include: • our inability to recruit and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any of our product candidates; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an internal sales and marketing organization. We will be completely dependent for the foreseeable future on third parties to manufacture our product candidates for commercial sale, and the commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices. We do not own or operate manufacturing facilities for the commercial production of our current product candidates. We currently rely on third-party contract manufacturers for all of our required raw materials, manufacturing devices, and active pharmaceutical ingredients for our preclinical research and clinical trials. Although we are able to manufacture finished product in our Groton, Connecticut facility for our clinical trials, we will rely on third parties for the manufacture of our finished product for commercial sale. We do not have long-term agreements with any of these third parties. We also do not have any current contractual relationship for commercial supplies. We intend to enter into agreements with third-party contract manufacturers and one or more backup manufacturers for future production. We are analyzing the feasibility of building manufacturing capabilities for future development and commercial quantities of any products that we develop. Such products will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval. In the meantime, we will be obligated to rely on contract manufacturers for our preclinical research and clinical trials and commercial production, if and when any of our product candidates are approved for commercialization. The facilities used by us or any contract manufacturer to manufacture our raw materials, manufacturing devices, active pharmaceutical ingredients and finished products must be approved by the FDA or comparable foreign regulatory authorities. Such approvals are subject to inspections that will be conducted after we submit a BLA to the FDA or their equivalents to other relevant regulatory authorities. Until such time, if ever, as we establish our own manufacturing facilities, we will not control the manufacturing process of our product candidates and will be completely dependent on our contract manufacturing partners for compliance with Current Good Manufacturing Practices, or cGMPs, for manufacture of our raw materials, manufacturing devices, active pharmaceutical ingredients and finished products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control, storage, distribution and record keeping relating to our product candidates. If our contract manufacturers do not successfully manufacture material that conforms to our specifications and the strict regulatory

requirements of the FDA or others, we will not be able to secure or maintain regulatory approval for product made at their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could significantly delay our clinical trials and impact our ability to develop, manufacture, obtain regulatory approval for or market our product candidates, if approved. Likewise, we could be negatively impacted if any of our contract manufacturers elect to discontinue their business relationship with us. Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our product candidates, delays, suspensions or withdrawals of approvals, inability to supply product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, manufacture, obtain regulatory approval for or market any of our product candidates, if approved. If, for any reason, these third parties are unable or unwilling to perform we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our required raw materials, manufacturing devices, active pharmaceutical ingredients or finished product or should cease doing business with us for any reason, we could experience significant delays in our clinical trials and significant interruptions in the supply of any of our product candidates or may not be able to create a supply of our product candidates at all. Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in development and clinical trial delays and lost sales. Additionally, we will rely on third parties to supply the raw materials needed to manufacture our product candidates. Any such reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to the operation of one of our contract manufacturers caused by problems with suppliers could delay our shipment of any of our product candidates, increase our cost of goods sold and result in delays in clinical trials or lost sales. Our business model includes the potential out-licensing of strains from our proprietary microbial library or our product candidates to other biopharmaceutical companies, however technology licensing in the biopharmaceutical industry is a lengthy process and subject to several risks and factors outside of our control, and we cannot forecast our ability to successfully out-license our technology or the length of time it takes to establish a new licensing relationship. Our business model includes the potential out-licensing or joint development of strains from our proprietary microbial library or our product candidates to other biopharmaceutical companies. Any such arrangement would typically begin with preliminary feasibility testing and evaluation by our potential partner or licensee. Assuming the feasibility testing is successful, our ability to convert the successful test into a commercial license or joint development agreement is dependent on a number of risks and factors, many of which are outside our control, including: • the rate of adoption and incorporation of new technologies, by members of the pharmaceutical industry generally; • our potential licensee's internal evaluation of the economic benefits of marketing a dermatological product that may be competitive with other products currently in development or commercial sale by our potential partner or licensee regardless of the perceived benefits or advantages of our technology or product; • our potential partner's / licensee's internal budgetary and product development issues, including their ability to commit the capital and human resources towards the development and commercialization of our technology or product; and • our potential partner's / licensee's willingness to accept our requirements for upfront fees and ongoing royalties. In addition, we believe that in many cases our potential partners or licensee may engage with us in the early-stage feasibility testing as part of their evaluation of multiple drug and drug delivery options and prior to making any decision or commitment to the development of a new drug product. Consequently, even if our platform is successful in early feasibility studies, our potential partner / licensee may decide, for reasons unrelated to the performance of our technology, not to enter into a license agreement with us. Therefore, we are unable to predict the degree to which our proposed licensing model will be successful. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates. We will face a potential risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk of such liability if we commercialize any of our product candidates. For example, we may be sued if any product we develop, including any of our product candidates, or any materials that we use in our product candidates allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. In the U. S., claims could also be asserted against us under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense of these claims would require us to employ significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand for any of our product candidates or any future products that we may develop; • injury to our reputation; • failure to obtain regulatory approval for our product

candidates; • withdrawal of participants in our clinical trials; • costs associated with our defense of the related litigation; • a diversion of our management's time and our resources; • substantial monetary awards to trial participants or patients; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • the inability to commercialize some or all of our product candidates; and • a decline in the value of our stock. As of the date of this report, we carry product liability insurance that we consider adequate for our current level of clinical testing and development. However, we will need additional product liability coverage at the time we commence commercial sale of our initial product. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. Although we will endeavor to obtain and maintain such insurance in coverage amounts we deem adequate, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies would also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. As a result, we may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs. Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data 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 were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and study subjects, 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. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyberattack. The number and complexity of these threats continue to increase over time. If a material breach of, or accidental or intentional loss of data from, 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. In addition, we could be subject to regulatory actions and / or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. 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. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm. We face significant competition from other biotechnology and pharmaceutical companies targeting medical dermatological indications, and our operating results will suffer if we fail to compete effectively. The dermatological therapies market is highly competitive and led by significant technologic developments. We anticipate that, if we are successful in obtaining regulatory approval of our candidates, we will face significant competition from other approved therapies or drugs that will become available in our industry. Even if another branded, generic, or OTC product is less effective, it may be quickly adopted by physicians and patients than our product based upon cost or convenience. Risks Related to Product Regulation Our success is entirely dependent on our ability to obtain the marketing approval for our product candidates by the FDA and the regulatory authorities in foreign jurisdictions in which we intend to market our product candidates, of which there can be no assurance. We are not permitted to market our product candidates as prescription pharmaceutical products in the United States until we receive approval of a BLA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of clinical trials of each biologic to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before a BLA is approved. Of the

large number of biologics in development, only a small percentage result in the submission of a BLA to the FDA and even fewer are eventually approved for commercialization. As of the date of this report, we have not submitted a BLA to the FDA or comparable applications to other regulatory authorities for any of our product candidates. Our success depends on our receipt of the regulatory approvals described above, and the issuance of such regulatory approvals is uncertain and subject to a number of risks, including the following:

- such authorities may disagree with the number, design, size, conduct or implementation of our clinical trials or any of our collaborators' clinical trials;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the use of results from studies that served as precursors to our current or future product candidates;
- the results of toxicology studies may not support the filing of an Investigational New Drug Application, or IND, or a BLA for our product candidates;
- the FDA or comparable foreign regulatory authorities or Institutional Review Boards, or IRBs, may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of our product candidates' safety and efficacy;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, European Medicines Agency, or EMA, or other regulatory agencies for us to receive marketing approval for any of our product candidates;
- the dosing of our product candidates in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our product candidates;
- the data collected from clinical trials may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval of our product candidates.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory approval for our product candidates for the foregoing, or any other reasons, will prevent us from commercializing our product candidates, and our ability to generate revenue will be materially impaired. In addition, the FDA, EMA or other regulatory agencies may also approve a product candidate for fewer or more limited indications than we request, may impose significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications or may grant approval contingent on the performance of costly post-marketing clinical trials or risk mitigation requirements. The FDA, EMA or other regulatory agencies may also not accept the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates. In December 2022, the U. S. Congress enacted a new law, the Modernization of Cosmetics Regulation Act of 2022, or MOCRA. MOCRA will require a cosmetic manufacturer or importer to: ensure that it has on hand substantiation of the safety of its products and ingredients; meet increased registration, record-keeping and reporting requirements; include fragrance and allergen information on its labeling; and be prepared to meet FDA's to be promulgated good manufacturing practices requirements. These additional requirements may impact budgets and timelines. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, a government agency's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. 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. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization. Our business model depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. All of our product candidates are in the early stages of development and as

of the date of this report we have not progressed any of our product candidates, other than ATR- 12 and ATR- 04, beyond performance characterization and animal testing. We may not be successful in obtaining approval from the FDA or comparable foreign regulatory authorities to start clinical trials for any of our other product candidates. If we do not obtain such approvals as presently planned, the time in which we expect to commence clinical programs for any product candidate will be extended and such extension will increase our expenses, delay our potential receipt of any revenues and increase our need for additional capital. Moreover, there is no guarantee that we will receive approval to commence human clinical trials or, if we do receive approval, that our clinical trials will be successful or that we will continue clinical development in support of an approval from the FDA or comparable foreign regulatory authorities for any indication. We note that most product candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Success in early phases of preclinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates. Therefore, our business currently depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. Results of preclinical studies of our product candidates may not be predictive of the results of future preclinical studies or clinical trials. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe, pure, and potent in humans. Before an IND can be submitted to the FDA and become effective, which is a prerequisite for conducting clinical trials on human subjects in the United States, a product candidate must successfully progress through extensive preclinical studies, which include preclinical laboratory testing, animal studies, and formulation studies in accordance with Good Laboratory Practices. Success in preclinical studies does not ensure that later preclinical studies or clinical trials will be successful. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Further, we or our investigators may have little control over whether subjects comply with important aspects of clinical trial protocols. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. In addition, the results of our preclinical animal studies may not be predictive of the results of outcomes in subsequent clinical trials on human subjects. Product candidates in clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies. If we fail to receive positive results in preclinical studies or clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects would be negatively impacted. Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of any of our product candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to: • the FDA or a comparable foreign regulatory authority failing to grant permission to proceed and placing the clinical study on hold; • subjects for clinical testing failing to enroll or remain enrolled in our trials at the rate we expect; • a facility manufacturing any of our product candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross- contaminations of product candidates in the manufacturing process; • any changes to our manufacturing process that may be necessary or desired; • subjects choosing an alternative treatment for the indications for which we are developing our product candidates, or participating in competing clinical studies; • subjects experiencing severe or unexpected drug- related adverse effects; • reports from clinical testing on similar technologies and products raising safety and / or efficacy concerns; • third- party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, cGMP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner; • inspections of clinical study sites by the FDA, comparable foreign regulatory authorities, or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications; • third- party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications; • one or more IRBs refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • deviations of the clinical sites from trial protocols or dropping out of a trial; • adding new clinical trial sites; • the inability of the CRO to execute any clinical

trials for any reason; and • government or regulatory delays or “ clinical holds ” requiring suspension or termination of a trial. Product development costs for any of our product candidates will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA, comparable foreign regulatory authorities, and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of any of our product candidates, its commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring competing products to market before we do, and the commercial viability of any of our affected product candidates could be significantly reduced. Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully commercialize the product and the revenue that we generate from its sales, if any, may be limited. If approved for marketing, the commercial success of our product candidates will depend upon each product’ s acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance for any of our product candidates will depend on a number of factors, including: • demonstration of clinical safety and efficacy; • relative convenience, dosing burden and ease of administration; • the prevalence and severity of any adverse effects; • the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies; • efficacy of our product candidates compared to competing products; • the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved; • new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility; • pricing and cost- effectiveness; • the inclusion or omission of our product candidates in applicable therapeutic and vaccine guidelines; • the effectiveness of our own or any future collaborators’ sales and marketing strategies; • limitations or warnings contained in approved labeling from regulatory authorities; • our ability to obtain and maintain sufficient third- party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third- party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and • the willingness of patients to pay out- of- pocket in the absence of third- party coverage or reimbursement or government pricing approvals. If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third- party payors on the benefits of our product candidates may require significant resources and may never be successful. In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render our product candidates not commercially viable. For example, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for any of our product candidates, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve any of our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the drug. Moreover, product approvals may be withdrawn for non- compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidates. Even if we obtain marketing approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates. Even if we obtain regulatory approval for any of our product candidates for an indication, the FDA or foreign equivalent may still impose significant restrictions on their indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time- consuming post- approval studies, including Phase 4 clinical trials, and post- market surveillance to monitor safety and efficacy. Our product candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post- market information. These requirements include registration with the FDA, as well as continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post- approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current cGMPs, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

The FDA has the authority to require a REMS as part of an BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and / or enrollment in a registry. With respect to sales and marketing activities related to our product candidates, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U. S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U. S. Anti-Kickback Statute, U. S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific / educational grant programs. If we participate in the U. S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U. S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U. S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries. In addition, if any of our product candidates are approved for a particular indication, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for our product candidates, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies 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 sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. If we or a regulatory agency discover previously unknown problems with a product candidate, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions: • restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls; • issuance of warning letters or untitled letters; • clinical holds; • injunctions or the imposition of civil or criminal penalties or monetary fines; • suspension or withdrawal of regulatory approval; • suspension of any ongoing clinical trials; • refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals; • suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or • product seizure or detention or refusal to permit the import or export of product. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad, and compliance with such regulation may be expensive and consume substantial financial and management resources. If we or any future marketing collaborators or contract manufacturers are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies or are not able to maintain regulatory compliance, it could delay or prevent the promotion, marketing or sale of our products, which would adversely affect our business and results of operations. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials, as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. If we fail to comply with the regulatory requirements in international markets and / or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Even though we may apply for orphan drug designation for a product candidate, we may not be able to obtain orphan drug marketing exclusivity. We believe that in some cases our products candidates may qualify for the FDA's orphan drug status. There is no guarantee

that the FDA will grant any future application for orphan drug designation for any of our product candidates, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to \$650,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for any of our product candidates in the indications for which we think they might qualify, if we elect to seek such applications. For the purposes of the rare pediatric disease program, a "rare pediatric disease" is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years or a rare disease or conditions within the meaning of the Orphan Drug Act. Under the FDA's rare pediatric disease priority review voucher, or RPD-PRV, program, upon the approval of an NDA or BLA for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for an RPD-PRV that can be used to obtain priority review for a subsequent NDA or BLA. The sponsor of the application may transfer (including by sale) the RPD-PRV to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. Congress has extended the RPD-PRV program until December 20, 2024, with potential for vouchers to be granted until 2026. This program has been subject to criticism, including by the FDA. As such it is possible that even if we have obtained qualification for an RPD-PRV, the program may no longer be in effect at the time of approval. Also, although priority review vouchers may be sold or transferred to third parties, there is no guaranty that we will be able to realize any value if we obtained, and subsequently were able to sell a priority review voucher. The RPD-PRV program is currently scheduled to sunset as of September 30, 2026. Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. In the United States, the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our product candidates and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 or, collectively, the ACA, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. The law also imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through

plan year 2025. The IRA also eliminates the “ donut hole ” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how such challenges, and the healthcare reform measures of the Biden administration will impact the ACA and our business. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In 2011, the U. S. Congress enacted the Budget Control Act of 2011, or the Budget Control Act, which included provisions intended to reduce the federal deficit. The Budget Control Act resulted in the imposition of 2 % reductions in Medicare payments to providers beginning in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 absent additional congressional action. However, pursuant to the CARES Act, and subsequent legislation, these reductions are suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations. If government spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA, to continue to function at current levels, which may impact the ability of relevant agencies to timely review and approve research and development, manufacturing and marketing activities, which may delay our ability to develop, market and sell any product candidates we may develop. In addition, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our anticipated product revenues. Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products. There have been several recent U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. On September 24, 2020, the FDA released a final rule providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U. S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On August 16, 2022, Congress enacted the Inflation Reduction Act of 2022 which contains several provisions relating to prescription drug costs, including requirements for federal government price negotiations, rebate requirements, and caps on out-of-pocket spending for Medicare Part D enrollees. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. On November 20, 2020, the HHS Office of Inspector General finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, the HHS Office of Inspector General added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others, yet removed safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. This rule (with exceptions) became effective January 19, 2021. We continue to evaluate what effect, if any, these rules will have on our business. CMS issued a final rule, effective on July 9, 2019, that requires direct-to-consumer advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product if it is equal to or greater than \$ 35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a public list. Any adopted health reform measure could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future. The delivery of healthcare in the European Union, or EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-

increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval. Both in the United States and in the EU, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues. Our ability to successfully market our product candidates will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our product candidates and related treatments. Countries in which any of our product candidates are sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell our product candidates profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope. Increasingly, third-party payors attempt to contain health care costs in ways that are likely to impact our development of products including: • failing to approve or challenging the prices charged for health care products; • introducing reimportation schemes from lower priced jurisdictions; • limiting both coverage and the amount of reimbursement for new therapeutic products; • denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and • refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval. Our relationships with customers and payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, primarily in the United States, that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable healthcare laws and regulations, include the following: • the federal Anti-Kickback Statute prohibits, among other things, the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (i) the referral of a person, (ii) the furnishing or arranging for the furnishing of items or services reimbursable under the Medicare, Medicaid or other governmental programs, or (iii) the purchase, lease or order or arranging or recommending purchasing, leasing or ordering of any item or service reimbursable under the Medicare, Medicaid or other governmental programs. 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. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; • the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for 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; • the Health Insurance Portability and Accountability Act, or HIPAA imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care 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; • the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services; • the Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which requires specified manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other "transfers of value" made to physicians. All such reported information is publicly available; • analogous state and non-U.S. laws and regulations, such as certain state anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and • regulation by CMS and enforcement by the HHS Office of Inspector General or the U.S. Department of Justice. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our future business activities could be subject to challenge under one or more of such laws. 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, exclusion from U. S. government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business with 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.

Risks Relating to Our Intellectual Property Rights

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights. Our commercial success will depend, in part, on our ability to prosecute and defend, if necessary, our patent rights against third- party challenges and successfully enforcing these patent rights against third party competitors. The patent positions of biotech companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in any patent applications filed by us or our licensors of patent rights. The patents and patent applications held by or licensed to us relating to our microbial platform and related technologies may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies. The degree of future protection afforded by the patent rights held by or licensed to us is uncertain, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed by us or in which we hold license rights or that we will not be involved in interference, opposition or invalidity proceedings before United States or foreign patent offices. Additionally, if we were to initiate legal proceedings against a third party to enforce a patent covering any of our product candidates, the defendant could counterclaim that such patent is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office, or the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post grant review and equivalent proceedings in foreign jurisdictions, e. g., opposition proceedings. Such proceedings could result in revocation or amendment of patents held by or licensed to us in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which, we, any licensor of our patent rights or 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 any of our product candidates. Such a loss of patent protection would have a material adverse impact on our business. We rely on know- how and trade secrets to protect technology, especially in cases where we believe patent protection is not appropriate or obtainable. However, know- how and trade secrets are difficult to protect. While we require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know- how. If we fail to obtain or maintain patent protection or trade secret protection for our product candidates or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability. Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts. Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third- party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third- party patents that may be infringed by commercialization of any of our product candidates or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize any of our product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time- consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and / or develop non- infringing technology; or
- require us to enter into royalty or licensing agreements.

Third parties may hold

proprietary rights that could prevent any of our product candidates from being marketed. Any patent- related legal action against us claiming damages and seeking to enjoin commercial activities relating to any of our product candidates or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market any of our product candidates or any future product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidates or any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing any of our product candidates or a future product candidate, which could harm our business, financial condition and operating results. We expect that there are other companies, including major biopharmaceutical companies, working in the areas competitive to our proposed product candidates which either has resulted, or may result, in the filing of patent applications that may be deemed related to our activities. If we were to challenge the validity of these or any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every issued United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. If we were to challenge the validity of these or any issued United States patent in an administrative trial before the Patent Trial and Appeal Board in the USPTO, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and / or court would find in our favor on questions of infringement, validity or enforceability. Even if we are successful, litigation could result in substantial costs and be a distraction to management. We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. As is commonplace in our industry, we will employ individuals who were previously employed at other biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non- competition or non- solicitation obligations) or claims that our employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Owning Our Common Stock

The market price of our shares may be subject to fluctuation and volatility. You could lose all or part of your investment. The market price of our common stock is subject to wide fluctuations in response to various factors, some of which are beyond our control. Since shares of our common stock were sold in our initial public offering, or IPO, in June 2023 at a price of \$ 150. 00 per share, the reported high and low sales prices of our common stock have ranged from \$ 5. 18 to \$ 0. 20 through February 24, 2025. The market price of our shares on the NYSE American may fluctuate as a result of a number of factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated variations in our and our competitors' results of operations and financial condition;
- changes in earnings estimates or recommendations by securities analysts, if our shares are covered by analysts;
- market acceptance of our product candidates;
- development of technological innovations or new competitive products by others;
- announcements of technological innovations or new products by us;
- publication of the results of preclinical or clinical trials for our product candidates;
- failure by us to achieve a publicly announced milestone;
- delays between our expenditures to develop and market new or enhanced products and the generation of sales from those products;
- developments concerning intellectual property rights, including our involvement in litigation brought by or against us;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products;
- changes in the amounts that we spend to develop, acquire or license new products, technologies or businesses;
- changes in our expenditures to promote our product candidates;
- our sale or proposed sale, or the sale by our significant stockholders, of our shares or other securities in the future;
- changes in key personnel;
- success or failure of our research and development projects or those of our competitors;
- the trading volume of our shares; and
- general economic and market conditions and other factors, including factors unrelated to our operating performance.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our shares and result in substantial losses being incurred by our investors. In the past, following periods of market volatility, public company stockholders have often instituted securities class action litigation. If we were involved in securities litigation, it could impose a substantial cost upon us and divert the resources and attention of our management from our business. Our failure to meet the continued listing requirements of the NYSE American could result in a delisting of our common stock. If we fail to satisfy the continued listing requirements of the NYSE American, such as the corporate governance requirements or the minimum closing bid price requirement, the NYSE American may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements 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 NYSE American's minimum bid price requirement or prevent future non- compliance with the NYSE American's listing requirements. Future capital raises may dilute your ownership and / or have other adverse effects on our operations. If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership will be reduced and these stockholders may experience substantial dilution. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our common stock and the terms of the

debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our intellectual property or candidate products, or to grant licenses on terms that are not favorable to us. Shares eligible for future sale may adversely affect the market for our common stock. As of the date of this report, we have 12,483,836 shares of common stock issued and outstanding, all of which are eligible for sale by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act, subject to certain limitations under Rule 144. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale report may have a material adverse effect on the market price of our common stock. We are an “emerging growth company” under the JOBS Act and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors. We are an “emerging growth company,” as defined in the JOBS Act and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to: • not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act; • reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; • exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments; and • extended transition periods available for complying with new or revised accounting standards. We have chosen to take advantage of all of the benefits available under the JOBS Act, including the exemptions discussed above. We cannot predict if investors will find our common stock less attractive because we may 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. We will remain an “emerging growth company” for up to five years, although we will lose that status sooner if our revenues exceed \$1.235 billion, if we issue more than \$1 billion in non-convertible debt in a three-year period, or if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30 in any future year. Our status as an “emerging growth company” under the JOBS Act may make it more difficult to raise capital as and when we need it. Because of the exemptions from various reporting requirements provided to us as an “emerging growth company,” we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected. We have not paid dividends on our common stock in the past and have no immediate plans to pay such dividends. We plan to reinvest all of our earnings, to the extent we have earnings, to cover operating costs and otherwise become and remain competitive. We do not plan to pay any cash dividends with respect to our common stock in the foreseeable future. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend. Therefore, you should not expect to receive cash dividends on our common stock. If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our shares, the price of our shares could decline. The trading market for our shares will rely in part on the research and reports that equity research analysts publish about us and our business, if at all. We do not have control over these analysts and we do not have commitments from them to write research reports about us. The price of our shares could decline if no research reports are published about us or our business, or if one or more equity research analysts downgrades our shares or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. We may be at an increased risk of securities class action litigation. Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business. We maintain director and officer insurance that we regard as reasonably adequate to protect us from potential claims; however, we are responsible for meeting certain deductibles under the policies and, in any event, we cannot assure you that the insurance coverage will adequately protect us from claims made. Further, the costs of insurance may increase and the availability of coverage may decrease. As a result, we may not be able to maintain our current levels of insurance at a reasonable cost, or at all. Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable. Provisions of our amended and restated certificate of incorporation and amended and restated bylaws and applicable provisions of Delaware law may delay or discourage transactions involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. The provisions in our amended and restated certificate of incorporation and amended and restated bylaws: • limit who may call stockholder meetings; • restrict our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed; • do not provide for stockholder action by written consent; • do not provide for cumulative voting rights; and • provide that all board vacancies may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum. Section 203 of the DGCL may limit our ability to engage in any business combination with a person who beneficially owns 15% or more of our outstanding voting stock unless certain conditions are satisfied. This restriction lasts for a period of three years following the share acquisition. These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirers at a premium over

prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

General Risk Factors Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters may materially impact reporting of our financial condition and results of operations. Accounting principles generally accepted in the United States and related accounting pronouncements, implementation guidelines, and interpretations we apply to a wide range of matters that are relevant to our business, such as accounting for long-lived asset impairment and share-based compensation, are complex and involve subjective assumptions, estimates and judgments by our management. Changes in these rules or their interpretation or changes in underlying assumptions, estimates or judgments by our management could significantly change or add significant volatility to our reported or expected financial performance. A potential failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, financial condition, and results of operations. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U. S. generally accepted accounting principles, or GAAP. Under standards established by the Public Company Accounting Oversight Board, or PCAOB, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. The PCAOB defines a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented, or detected and corrected, on a timely basis. We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for our second annual report on Form 10-K filed with the SEC and in each year thereafter. Our auditors will also need to attest to the effectiveness of our internal control over financial reporting at such time as we are an accelerated filer or large accelerated filer and no longer an emerging growth company or smaller reporting company. If we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be adversely affected, and we could become subject to litigation or investigations by the stock exchange on which our common stock are listed, the SEC or other regulatory authorities, which could require additional financial and management resources and could have a material adverse effect on our business, financial condition, and results of operations. The limited amount of public company experience of our management team could adversely impact our ability to comply with the reporting requirements of U. S. securities laws, which could have a materially adverse effect on our business. Our officers have limited public company experience, which could impair our ability to comply with legal and regulatory requirements such as those imposed by Sarbanes-Oxley Act. Such responsibilities include complying with federal securities laws and making required disclosures on a timely basis. Any such deficiencies, weaknesses or lack of compliance could have a materially adverse effect on our ability to comply with the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, which is necessary to maintain our public company status. If we were to fail to fulfill those obligations, our ability to continue as a U. S. public company would be in jeopardy in which event you could lose your entire investment in our Company. We identified material weaknesses in our internal control over financial reporting, and we may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we otherwise fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are 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 conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retrospective 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 shares of common stock. There is also a risk that neither we nor our independent registered public accounting firm (when applicable in the future) will be able to conclude within the prescribed timeframe that internal controls over financial reporting is effective as required by Section 404. As a result, investors could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. During the preparation of our financial statements included in this report, we and our independent registered public accounting firm identified a material weakness as it relates to a lack of adequate segregation of accounting functions. We are in the process of implementing measures designed to improve our internal control over financial reporting and remediate this material weakness. We intend to increase staffing within our accounting infrastructure sufficient to facilitate proper segregation of accounting functions. We may identify future material weaknesses in our internal controls over financial reporting or fail to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley, and we may be unable to accurately report our financial results, or report them within the timeframes required by law or stock

exchange regulations. We cannot assure that our existing material weakness will be remediated or that additional material weaknesses will not exist or otherwise be discovered, any of which could adversely affect our reputation, financial condition and results of operations. We have and will continue to incur significant increased costs as a result of being a public company that reports to the SEC and our management will be required to devote substantial time to meet compliance obligations. As a public company reporting to the SEC, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to reporting requirements of the Exchange Act and the reporting and governance provisions of the Sarbanes- Oxley Act and the Dodd- Frank Wall Street Reform and Protection Act, as well as rules subsequently implemented by the SEC, that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. There are significant corporate governance and reporting provisions in these laws that will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel will need to devote a substantial amount of time to these regulations. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board or Board committees or as executive officers. Unfavorable geopolitical and macroeconomic developments could adversely affect our business, financial condition or results of operations. Our business could be adversely affected by conditions in the U. S. and global economies, the United States and global financial markets and adverse geopolitical and macroeconomic developments, including rising inflation rates, the continuing adverse impacts of the COVID- 19 pandemic, the Ukrainian / Russian and Israeli / Palestinian conflicts and related sanctions, bank failures, and economic uncertainties related to these conditions. For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In response to rising inflation, the U. S. Federal Reserve has raised, and may again raise, interest rates, which, coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks. Additionally, financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022 and the eruption of the Israeli / Palestinian conflict in October 2023, including as a result of economic sanctions and export controls against Russia and countermeasures taken by Russia. The full economic and social impact of these sanctions and countermeasures, in addition to the ongoing military conflicts in Ukraine and Gaza, which could conceivably expand, remains uncertain; however, both the conflicts and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability, and / or supply chain continuity, in both Europe and globally, and has introduced significant uncertainty into global markets. While we do not currently operate in Russia, Ukraine or the Middle East, as the adverse effects of these conflicts continue to develop our business and results of operations may be adversely affected. ~~Item 1B. Unresolved Staff Comments~~