

Risk Factors Comparison 2025-03-27 to 2024-02-29 Form: 10-K

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Investing in shares of our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all of the other information contained in this Annual Report on Form 10-K **and in our other filings with the SEC** before making an investment decision. The occurrence of any of the following risks could materially and adversely affect our business, financial condition, reputation, or results of operations. In such case, the trading price of shares of our common stock could decline, and you may lose all or part of your investment. It is not possible to predict or identify all such risks; our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider to present significant risks to our operations. Therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face. **Moreover, some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past, and instead reflect our beliefs and opinions as to the factors, events or contingencies that could materially and adversely affect us in the future.**

Summary of Key Risk Factors

- We are ~~a an early-clinical~~ **preclinical**-stage biotechnology company and have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale, **have never generated revenue from product sales**, and may never achieve or maintain profitability.
- We will require additional funding in order to complete development of our product ~~candidate(s)~~ **candidate (s), including SL- 325**, and commercialize our products, if approved. Additional funding may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs **and any future clinical trials**, our efforts to access manufacturing capacity, and ~~our any~~ **commercialization efforts**.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- **We are substantially dependent on the success of our lead product candidate, SL- 325, and our anticipated clinical trials of such product candidate may not be successful.**
- Our ~~product candidate (s)~~ **product candidate (s)** compounds, including those from our ~~ARC platform~~, are ~~based in preclinical stages of development and may fail in development or suffer delays. We depend on the successful initiation novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us~~ **based in preclinical stages of development and may fail in development or suffer delays. We depend on the successful initiation** ~~novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~our product candidates to advance our~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~predict the time and cost of product development plans and potential for regulatory approval. We may not be successful in our efforts to use and expand our technology platforms to develop and commercialize our compounds and product candidates, or may experience significant delays in doing so.~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidate(s) or any future product candidates, which would prevent or delay or limit both the scope of regulatory approval and our ability to successfully commercialize.~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~Interim-Preclinical and clinical development is a lengthy and expensive process that is subject to delays and uncertain outcomes, topline, or preliminary data from our and results of earlier studies and trials may not be predictive of future clinical trial results. If preclinical studies and clinical trials of that we announce or our publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~Clinical drug development is a lengthy and expensive process with uncertain outcomes. If clinical trials of our product candidate(s) are prolonged or delayed, we or any collaborators may be unable to obtain required regulatory approvals, and, therefore, be unable to complete the development of and commercialize our product candidate(s) on a timely basis or at all.~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~We may not be successful in our efforts to identify or discover additional product candidates.~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~We face competition from entities that have developed or may develop programs for the diseases addressed by product candidates developed by us.~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~Our product candidate(s) may have serious adverse, undesirable, or unacceptable side effects or other properties that may delay or prevent marketing approval.~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~If we experience delays or difficulties initiating clinical trial sites or enrolling patients in our planned clinical trials, our research and development efforts, business, financial condition, and results of operations could be materially and adversely affected.~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~The development and commercialization of biopharmaceutical products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidate(s) on a timely basis, if at all, our business will be substantially harmed. We operate in highly-competitive and rapidly-changing industries, which may result in others discovering, developing, or commercializing competing products before or more successfully than we do.~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~We rely on third parties to supply raw materials and to manufacture our product candidate(s). The manufacture of our product candidate(s) is complex and our third-party manufacturers may encounter difficulties in production, which could delay or entirely halt their ability to supply our product candidate(s) for clinical trials or, if approved, for commercial sale.~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~Our success depends upon our ability to obtain and maintain patents and other intellectual property rights to protect our technology, including SL- 325 product candidates from our ARC platform, methods used to manufacture those our product candidate(s), formulations thereof, and the methods for treating patients using those product candidate(s).~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~Economic downturns, inflation, fluctuating interest rates, changes in trade policies, including tariffs or other trade restrictions or the threat of such actions, natural disasters, Public-public health crises such as pandemics or other events could materially and adversely affect our business operations, workforce, product development activities, research and development activities, preclinical and clinical trials, and financial condition.~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~Risks Related to Our Business~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~Our Financial Condition and Capital Requirements~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~We are a preclinical-stage biotechnology company and will need to raise substantial additional capital to continue to fund our operations in the future. We have based our estimates on assumptions that may prove to be wrong, and could exhaust our available financial resources sooner than we currently anticipate.~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us** ~~Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We have incurred significant operating losses since inception. For the years ended December 31, 2024 and 2023 and 2022, we reported a net loss of \$ 75.4 million and \$ 87.3 million and \$ 101.9 million, respectively. As of December 31, 2023-2024, we had an accumulated deficit of \$ 306.381.3-7 million. We expect to continue to incur significant operating losses for the foreseeable future.~~ **novel technologies that are unproven and completion of clinical trials may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us**

including as our product candidate (s) enter clinical trials. We expect to invest significant funds into the research and development of our current programs to determine the potential to advance product candidate (s) to regulatory approval. To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. We may never succeed in these activities and, even if we do, we may never generate revenue that is sufficient to achieve profitability. We **expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we:**

- continue the preclinical development and initiate the clinical development of our lead product candidate, SL- 325, and any other potential product candidates;
- continue efforts to discover and develop new product candidates;
- continue the manufacturing of our product candidate (s) or increase volumes manufactured by third parties;
- initiate additional preclinical and nonclinical studies or clinical trials for our product candidate (s);
- seek regulatory and marketing approvals for our product candidate (s);
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which it may obtain marketing approval and market for ourselves;
- seek to maintain, protect, and expand our intellectual property portfolio; and
- experience any delays or encounter issues with the development and potential regulatory approval of our clinical and product candidate (s) such as safety issues, manufacturing delays, clinical trial accrual delays, longer follow-up for planned studies or trials, additional major studies or trials, or supportive trials necessary to support marketing approval.

We will require additional funding in order to complete development of our product candidates—**candidate (s), including SL- 325,** and commercialize our products, if approved. Additional funding may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs and other operations. Based on our current business plans, we estimate that our existing cash and cash equivalents and investments will enable us to fund our operating expenses into ~~2026~~ **2027**. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect, requiring us to seek additional funds sooner than planned through public or private equity or debt financings or other sources, such as strategic collaborations. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may materially and adversely affect the development of our product candidates. Our ability to raise additional funds will depend on financial, economic, and market conditions and other factors, over which we may have no or limited control. Additional funds may not be available when we need them, on terms that are acceptable to us or at all. **Raising additional capital may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidate (s).** If we raise additional capital through the sale of equity, including through our “at-the-market” ~~offerings~~ **offering facility** (the “ATM Facility”), or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders’ rights as holders of our common stock. In addition, the possibility of such issuance may cause the market price of our common stock to decline. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take certain actions, **such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends,** which could materially and adversely impact our ability to conduct our business. **If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our research programs or product candidate (s) or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to third parties to develop and market product candidate (s) that we would otherwise prefer to develop and market ourselves.**

Our compounds, including those from our ARC platform, are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval. We may not be successful in our efforts to use and expand our technology platforms to develop and commercialize our current and future product candidates, or may experience significant delays in doing so. A key element of our strategy is to use and expand our proprietary technologies, including our ARC platform, to build a pipeline of product candidates and progress these compounds and product candidates through preclinical and clinical development. Although our research and development efforts to date have resulted in a pipeline of product candidates and potential product candidates directed at various cancers and other indications, we have not received regulatory approval for any of our product candidates. The scientific research that forms the basis of our efforts to develop product candidates with our proprietary technologies, including those from our ARC platform, is still ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our platforms is both preliminary and limited. Given the novelty of our technologies, we intend to work closely with the FDA and other regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies. To our knowledge, our dual-sided fusion protein product candidates have not previously been tested in humans and may have properties that negatively impact safety or efficacy, such as greater immunogenicity when compared to existing therapeutics. Moreover, our product candidates may have unexpected biological interactions when administered in vivo. Finally, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of our product candidates, which could result in a longer than expected regulatory review process, increase our expected development costs, and delay or prevent commercialization of our product candidates. The successful development of our product candidates will depend on several factors, including the successful and timely completion of clinical trials and preclinical studies; successful patient enrollment in clinical trials; receipt of regulatory approvals and marketing authorizations; commercially viable manufacturing processes; and our ability to demonstrate the safety and efficacy of our product candidates. Our ability to generate revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product, which could result in significant harm to our financial position and materially and adversely affect our share price. Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel. ~~We expect to continue to expand our capabilities, and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.~~ Our success depends upon the

continued contributions of our key management, scientific, and technical personnel, many of whom have been instrumental for us and have substantial experience with our product candidates— **candidate (s)** and related technologies. Although we have employment agreements with certain of our key employees, including our Chief Executive Officer, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. **We expect to experience periods of growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical operations, business development, manufacturing, regulatory affairs, quality assurance, human resources, legal, accounting and finance, and, ultimately, sales and marketing. The competition for qualified personnel in the biotechnology and pharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled scientific, technical, and managerial employees. If our recruitment and retention efforts are unsuccessful, when needed, in the future, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business. To manage any future growth, we must continue to implement and improve our managerial, operational, and financial systems, and expand our facilities. Due to our limited financial resources and the limited experience of our management team in managing a growing company, we may not be able to effectively manage the expansion of our operations systems and facilities. These activities may lead to significant costs and may divert our management and other resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. In addition, we are a small company with limited resources, our business prospects are uncertain, and our stock price is volatile. For some or all of the foregoing reasons, we may not be able to recruit all of the management, technical, and other personnel that we require or we may be unable to retain all of our existing personnel. In such event, we may be required to limit our growth and expansion efforts and our business and financial results may suffer. Since our inception in 2016, we have devoted a significant portion of our resources to developing our product candidates, our other research and development efforts, building our intellectual property portfolio, raising capital, and providing general and administrative support for these operations. We have not yet demonstrated our ability to successfully complete product development activities, complete late-stage clinical trials (including Phase 3 or other pivotal clinical trials), obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions you or we may make about our future success or viability may not be as accurate as they could be if we had a longer operating history.** Risks Related to the Development and Clinical Testing of Our Product Candidates

Our We are substantially dependent on the success of our lead product candidate, SL- 325, and our anticipated clinical trials of such product candidate (s) may fail not be successful. Our lead product candidate, SL- 325, is in preclinical development, and if that product candidate is not successful, our business could be materially impacted. While we have other preclinical programs, such as SL- 425, there is no guarantee that these programs will advance into clinical development. Our future success is substantially dependent on our ability to demonstrate develop and timely obtain marketing approval for, and then successfully commercialize, SL- 325. We are investing the majority of our efforts and financial resources into the research and development of SL- 325, SL- 425, and other DR3 antagonists, including bispecific antibodies targeting DR3 together with another biologically relevant target. Our product candidates, including our lead product candidate, SL- 325, are in the early stages of development and will require substantial preclinical evidence of the safety and efficacy of our clinical development and testing, manufacturing process development, improvement and validation, and regulatory approval prior to commercialization and before we generate any revenues from product sales. The success of our product candidates— candidate (s) will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future product candidates collaborator. Of the large number biologics and drugs in development in the pharmaceutical industry, which would prevent only a small percentage result in the submission of a biologics license application (“ BLA ”) to the FDA or marketing authorization application (“ MAA ”) to the European Medicines Agency (“ EMA ”), and even fewer are approved or for delay or limit both the scope of commercialization. Furthermore, even if we do receive regulatory approval and to market any of our product candidates, any such approval may be subject to limitations on the indicated uses for which we may market the product, our— or ability limitations related to its distribution, or be conditional on future development activities and clinical results. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, there can be no assurance that any of our product candidates will be successfully developed or commercialized. If we or any of our future development partners are unable to develop, or obtain regulatory approval, or, if approved, successfully commercialize, any of our product candidates, we may not be able to generate sufficient revenue to continue the operation of our business. For Our product candidate (s) are in preclinical stages of development and may fail in development or suffer delays. We depend on the successful initiation and completion of clinical trials for our product candidate (s) to advance our product development plans. We have no products on the market, and our product candidate (s) are in preclinical stages of development and have not been tested in humans. As a result, we expect it will be years before we can obtain the requisite regulatory approvals— approval for to market and sell commercialize any product candidates— candidate, we if ever. We must initiate demonstrate through extensive preclinical studies and complete clinical trials that our compounds demonstrate the safety and investigational drug efficacy of our products— product are candidates in humans, and we do not yet know if our lead product candidate, SL - 325, will be safe and or effective for use in humans each targeted indication. Clinical testing is expensive, difficult to design and implement, and can takes— take many years to complete, and its— is uncertain as to outcome is inherently uncertain. The process A failure of one or more obtaining regulatory approval is expensive, often taking many years following the commencement of our clinical trials, and can vary substantially based upon the type, complexity, and novelty of the product candidates involved, as well as the target indications, patient population, and regulatory agency. As mentioned herein, our occur at any stage product candidates and technology platforms are novel and entail significant complexity. Clinical trials that we conduct may not demonstrate the efficacy and safety that is necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future testing. The outcome of preclinical testing and early clinical trials may not be predictive are inconclusive with respect to the efficacy of our product candidates the success of later clinical trials, if we and interim results of a clinical trial do not meet the necessarily predict final results. Moreover, clinical preclinical endpoints with statistical and clinically meaningful significance, or if there are safety

concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. Additionally, any safety concerns observed in any one of our clinical trials could limit the prospects for regulatory approval of that product candidate or other product candidates in any indications. Even if our clinical trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and **many companies** we cannot guarantee that **have believed the their** FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we are able to submit our product candidates **performed satisfactorily** for approval. Moreover, results that are acceptable to support approval in one jurisdiction may be deemed inadequate to support regulatory approval in other jurisdictions. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate in a manner that does not meet our expectations, which limitations may reduce its commercial potential. From time to time, we have publicly disclosed, and we may publicly disclose again in the future, interim, topline, or preliminary data from our preclinical studies and clinical trials, which **have nonetheless failed to obtain marketing approval for their products. Preclinical and clinical development is based on a lengthy** preliminary analysis of then-available data, and the **expensive process that is subject to delays and uncertain outcomes, and** results and related findings and conclusions are subject to change following a more comprehensive review of **earlier preclinical** the data related to the particular trial. The interim, topline, or preliminary results that we have reported or may report in the future may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. For example, safety, pharmacokinetic, and pharmacodynamic data are different than, and may not be predictive of, clinical efficacy endpoints. In addition, at times we have access to additional data, in part because our trials are open-label, beyond what has been publicly disclosed. As a result, interim, topline, or preliminary data should be viewed with caution until the final data are available. Interim, topline, or preliminary data from clinical trials that we may **not be predictive** complete are subject to the risk that one or more of the **future** clinical outcomes may materially change as patient enrollment continues and more patient data become available. Material **trial results** differences between interim, topline, or preliminary data and final data could significantly harm our business prospects. **If preclinical studies and** Further, disclosure of interim, topline, or preliminary data by us or by our competitors could impact our ability to enroll our clinical trials and influence industry expectations, which could result in volatility in the price of **our product candidate (s) are prolonged our- or common stock delayed, we may be unable to obtain required regulatory approvals, and affect, therefore, be unable to complete the development of and commercialize our product candidate (s) on a timely basis our- or at all ability to raise additional capital.** It is impossible to predict when or if any of our product candidates- **candidate (s)** will prove **safe and effective and safe** in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates- **candidate (s)** in humans. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and a failure of one or more clinical trials can occur at any **time or stage of testing the preclinical study or clinical trial process. Additionally, there is no guarantee that our IND filing (s) will be accepted by the FDA, or comparable foreign regulatory authorities, or that these filings (s) will be accepted within our expected timelines**. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. The design of a clinical trial can determine whether its results will support approval of a product candidate, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their compounds and product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. In addition, the results of our preclinical animal studies, including our non-human primate studies, may not be predictive of the results of outcomes in subsequent clinical trials on human subjects. Product candidates in clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies. **Additionally, all of our trials, including our ongoing Phase 1 trials evaluating SL-172154, are open-label trials in which both the patient and investigator know whether the patient is receiving the investigational product candidate or an existing approved therapy. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect, as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open-label trials will not be replicated in later placebo-controlled trials.** We could also encounter delays if a clinical trial is suspended or terminated by us, by the independent institutional review boards of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. If we are required to conduct additional clinical trials or other testing of our product candidates- **candidate (s)** beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates- **candidate (s)**, if the results of these trials are not positive or are only moderately positive, or if there are safety concerns, our business and results of operations may be materially and adversely affected, and we may incur significant additional costs. **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, delay or limit both the scope of regulatory approval and our ability to successfully commercialize. To obtain the requisite regulatory approvals to market and sell any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our compounds and investigational drug products are safe and effective for use in each targeted indication in humans. Clinical testing is expensive and takes many years to complete, and its outcome is inherently uncertain. The process of obtaining regulatory approval is expensive, often taking many years following the commencement of clinical trials, and can vary substantially based upon the type, complexity, and novelty of the product candidates involved, as well as the target indications, patient population, and regulatory agency. Clinical trials that we conduct may not demonstrate the efficacy and safety that is necessary to obtain regulatory approval to market our product candidate (s). If the results of our future clinical trials are inconclusive with respect to the efficacy of our product candidate (s), if we do not**

meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidate (s), we may be delayed in obtaining marketing approval, if at all. For example, with respect to a legacy product candidate, SL- 172154, we previously discontinued development when promising complete remission rates from interim data did not translate into improved overall survival in subsequent topline data. Additionally, any safety concerns observed in any one of our future clinical trials could limit the prospects for regulatory approval of that product candidate or other product candidates in any indications. Even if our clinical trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we are able to submit our product candidate (s) for approval. Moreover, results that are acceptable to support approval in one jurisdiction may be deemed inadequate to support regulatory approval in other jurisdictions. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate in a manner that does not meet our expectations, which limitations may reduce its commercial potential. The success of our business depends primarily upon our ability to identify, develop and commercialize products. Our research programs may fail to identify other potential product candidates for clinical development for a number of reasons. For example, our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to lack efficacy, have harmful side effects, or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that may ultimately prove to be unsuccessful. We face competition from entities that have developed or may develop programs for the diseases addressed by product candidate (s) developed by us. The development and commercialization of drugs is highly competitive. Product candidate (s) developed by us, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. We compete with a variety of biopharmaceutical companies as well as academic institutions, governmental agencies, and public and private research institutions, among others. Many of the companies with which we are currently competing or will compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals, and marketing than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, recruiting participants for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our product candidate (s). Our competitors have developed, are developing or will develop programs and processes competitive with our programs and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments. Our success will depend partially on our ability to develop and commercialize products that have a competitive safety, efficacy, dosing and / or presentation profile. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, have a more attractive dosing profile or presentation or are less expensive than the products we develop, or if our competitors develop competing products or if biosimilars enter the market more quickly than we do and are able to gain market acceptance. Certain of our programs may compete with our other programs, which could negatively impact our business and reduce our future revenue. We are developing programs which may compete with one another. For example, we are developing SL- 325 and may choose to develop SL- 425 for the same indication: inflammatory bowel disease, and may in the future develop our programs for other inflammatory and immune-mediated diseases. Developing multiple programs for a single indication may negatively impact our business if the programs compete with each other. For example, if multiple programs are conducting clinical trials at the same time, they could compete for the enrollment of patients. In addition, if multiple programs are approved for the same indication, they may compete for market share, which could limit our future revenue. Our product candidates may have serious adverse, undesirable, or unacceptable side effects or other properties that may delay or prevent marketing approval and our ability to market and derive revenue from our product candidates— candidate (s) could be compromised. Undesirable side effects that may be caused by our product candidates— candidate (s) could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. While we believe that the targeted nature of **Our product candidate (s), including our dual-lead product candidate, SL- 325** sided fusion proteins may carry a lower risk of overstimulating the immune system and causing a cytokine storm (a side effect associated with certain other antibody therapies), **have not been tested in humans, and we do not yet know if it will have serious, undesirable, or unacceptable** enough clinical data and experience with these molecules in humans to fully anticipate side effects. Accordingly, we may experience unexpected side effects and / or higher levels of known side effects in clinical trials, such as cytokine storms associated with certain immunotherapies or red blood cell lysis associated with some CD47 targeting therapies. Results of our **preclinical studies or** clinical trials could reveal a high and unacceptable severity and / or prevalence of these or other side effects. In such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign authorities could order us to cease further development or deny approval of our product candidates— candidate (s) for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may **significantly** harm our business **and**, financial condition **significantly and results of operations** . Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates— candidate (s) may only be uncovered with a significantly larger number of patients exposed to the product candidate. **We have not yet initiated clinical trials for our product candidate (s), including our lead product candidate, SL- 325.** Successful and timely completion of **our planned** clinical trials will require that we initiate our clinical trial sites in a timely manner and enroll a sufficient number of **subjects or patient patients** candidates . Trials **have been and** may **continue to** be subject to delays for a variety of reasons, including as a result of delays to clinical trial site start up and initiation, patient enrollment taking longer than anticipated, fewer than expected patients who meet enrollment eligibility

criteria, patient withdrawal, or AEs. Our clinical trials **may** compete with other clinical trials that are in the same therapeutic areas as our product ~~candidates-~~ **candidate (s)** and / or that seek to enroll the same specific patient populations as our clinical trials, which reduces the number and types of patients available to us. We **may** also compete with head- to- head clinical trials, in which patients may prefer to participate, which may further reduce the number of patients available to us. **Moreover, enrolling patients in clinical trials for cancer therapies is challenging, as cancer patients will first receive the applicable standard of care. Many patients who respond positively to the standard of care therapy (and thus do not enroll in clinical trials) are believed to have tumor types that may have responded well to our product candidates. This may limit the number of eligible patients able to enroll in our clinical trials and could extend development timelines or increase costs for these programs. Patients who fail to respond positively to the standard of care treatment will be eligible for clinical trials of unapproved drug candidates. However, these patients may have either compromised immune function from prior administration of chemotherapy or an enhanced immune response from the prior administration of checkpoint inhibitors. Either of these prior treatment regimens may render our therapies less effective in clinical trials. We have sought and may continue to seek to mitigate these effects in the future through modification of enrollment eligibility criteria. Additionally, patients who have failed approved therapies will typically have more advanced cancer and a poorer long- term prognosis. If we are unable to initiate or adequately enroll our clinical trial sites in the United States, the United Kingdom of Great Britain, Canada, and Europe, our clinical trials may be delayed. Receiving approval for and establishing clinical trial sites in other countries may be more challenging or lengthy than in the United States. As a result of any of the aforementioned factors, we may in the future decide to use clinical trial sites in other parts of the world. It may be more difficult to control international clinical trials and the results may be less reliable. In addition, if the international clinical trial was conducted in a country with lower quality healthcare than in developed countries, the patients may experience side effects not experienced by patients in developed countries. Delays in the completion of any clinical trial of our product ~~candidates-~~ **candidate (s)** will increase our costs, slow down our product candidate development and approval process, and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product **candidate (s). We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates** that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial resources, we focus our research and development efforts on certain selected product ~~candidate-~~ **candidate(s)**, including SL-325. As a result, we may forgo or delay pursuit of opportunities with other product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. In addition, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.**

Risks Related to Our Regulatory Environment The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting (including the submission of safety and other post- marketing information and reports), and other possible activities relating to our product ~~candidate-~~ **candidate(s)** are subject to extensive regulation by the FDA and by comparable regulatory authorities outside the United States. Obtaining approval of a BLA can be a lengthy, expensive, and uncertain process, and as a company we have no experience with the preparation of a BLA submission or any other application for marketing approval. This lengthy approval process may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. See “ Business — Government Regulation — BLA Submission and Review .” In addition, the FDA or comparable foreign authorities may change the requirements for clinical development and approval, which may alter our clinical development plans and increase our costs. **For example, the FDA published guidance in January 2023 on “ Project Optimus,” an initiative to improve dose selection in oncology drug development with the goal of optimizing the design of early dose- finding trials.** If the FDA does not believe we have sufficiently demonstrated that the selected doses for our product candidates maximize not only the efficacy of such candidate, but the safety and tolerability as well, our ability to progress our clinical trials and ultimately commercialize a product candidate may be delayed and our costs may be increased. Any regulatory approvals that we may receive for our programs will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the program, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post- approval study or risk management requirements. For example, the FDA may require a risk evaluation and mitigation strategy in order to approve our programs, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or comparable foreign regulatory authorities approve our programs, our programs and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as on- going compliance with current cGMPs and GCPs for any clinical trials that we conduct following approval. **If we or a regulatory authority discover previously unknown problems with a** **We may seek designations under FDA programs designed to facilitate and potentially expedite product candidate development**, such as **Fast Track or Breakthrough Therapy Designation. If we decide to pursue a Fast Track or Breakthrough Therapy Designation by the FDA, it may not lead to a faster development or regulatory review or approval process. We may seek a Fast Track or Breakthrough Therapy Designation for a product candidate. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for one or both of these designations, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track or Breakthrough Therapy Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track or Breakthrough Therapy Designation if it believes that the designation is no longer supported by data from our clinical development program. See the section titled “ Business — Government Regulation — Expedited Development and Review Programs ” for a**

more detailed description of the process for seeking Fast Track and / or Breakthrough Therapy Designation. Disruptions at the FDA and other government agencies could negatively affect the review of our regulatory submissions, which could negatively impact our business. The ability of the FDA to review and approve regulatory submissions can be affected by a variety of factors, including disruptions caused by government shutdowns and public health crises. Such disruptions could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on events of unanticipated severity or frequency, or problems with the business. Our research and development facilities—activities where the product is manufactured, could be affected or delayed as a result of possible regulatory authority may impose restrictions on that product, the manufacturing facility or animal testing. Certain laws and regulations require us to test, including requiring recall or our compounds withdrawal of the product from the market or suspension of manufacturing, restrictions on animals before initiating our ability to conduct clinical trials involving humans, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. To The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidate (s) and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. Our product candidates for which we intend to seek approval as biologics may face competition sooner than anticipated. The Patient Protection and Affordable Act, as amended by the extent Healthcare and Education Reconciliation Act (the activities “ACA”), includes a subtitle called the Biologics Price Competition and Innovation Act of animal rights groups 2009 (“BPCIA”), which created an abbreviated approval pathway for biological products that are biosimilar to successful, or our research interchangeable with an and development activities FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or “biosimilar” product may not be interrupted submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, delayed the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for or become more expensive the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. We believe that our product candidate (s), if Current and future laws and regulations may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain. Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our product candidates- candidate (s) or additional pricing pressures. In August 2022, President Biden signed into law the IRA, which, among other provisions, included several measures intended to lower the cost of prescription drugs and enact related healthcare reforms. We cannot be sure whether additional legislation or rulemaking related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future. We may expend our limited resources..... delayed, or become more expensive. Our business operations and current and future relationships with healthcare professionals, principal investigators, consultants, vendors, customers, and third-party payors are subject to applicable healthcare laws, which could expose us to penalties. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates- candidate (s), if approved. See “Business — Government Regulation — Other Healthcare Laws and Compliance Requirements” for a more detailed description of the laws that may affect our ability to operate. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, as well as damages, fines, exclusion from government-funded healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming, may require significant personnel resources, and may impair our business even if we are successful in defending against such claims. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Our employees, independent contractors, principal investigators, contract research organizations (“CROs”), consultants, commercial partners, suppliers, and vendors acting for us or on our behalf may engage in misconduct or other improper activities, including noncompliance with applicable laws and regulations. We have adopted a code of conduct, but it is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Risks Related to Commercialization of Our Product Candidates We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing, or commercializing competing products before or more successfully than we do. Our success is highly dependent on our ability to expeditiously discover, develop, and obtain marketing approval for new and innovative products on a cost-

effective basis and market them successfully. With the proliferation of new therapies, including oncology drugs and immuno-therapies, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological innovation, we may be unable to compete effectively. The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small. Cancer therapies are sometimes characterized by line of therapy (first, second, third, fourth, etc.), and the FDA often initially approves new therapies only for use in a particular line or lines of therapy. For example, we may initially seek approval of our product candidates as a third-line therapy for patients who have failed other approved treatments. We may subsequently seek approval as a second- and first-line therapy. There is no guarantee that our product candidates, even if initially approved, would be subsequently approved as a second or first line therapy. Because the potentially addressable patient target population for our product candidates may be limited to patients who are ineligible for or have failed prior treatments, even if we obtain significant market share for our product candidates, we may never achieve profitability. We currently are pursuing the development of our product candidates in combination with other approved therapeutics. If the FDA revokes approval of any such therapeutic, or if safety, efficacy, manufacturing, or supply issues arise with any therapeutic that we use in combination with one of our product candidates in the future, we may be unable to further develop and / or market our product candidate or we may experience significant regulatory delays or supply shortages, and our business could be materially and adversely affected. We currently are pursuing the development of our product candidates in combination with other approved therapeutics, and we have commenced clinical trials of our product candidates in combination with other approved therapeutics in the future. We have not developed or obtained regulatory approval for, nor will we manufacture or sell, any of these approved therapeutics. In addition, the combinations have not have been previously tested and may, among other things, fail to demonstrate synergistic activity, fail to achieve superior outcomes relative to the use of single agents or other combination therapies, exacerbate AEs associated with one of our product candidates when used as monotherapy, or fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy. If the FDA revokes its approval of any combination therapeutic, we will not be able to continue clinical development of or market any product candidate in combination with such revoked therapeutic. If safety or efficacy issues arise with therapeutics that we seek to combine with, we could experience significant regulatory delays, and the FDA could require us to redesign or terminate the applicable clinical trials. In addition, we may need, for supply, data referencing, or other purposes, to collaborate or otherwise engage with the companies who market these approved therapeutics. If we are unable to do so on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate or indication, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities. Our product candidates for which we intend to seek approval may face competition sooner than anticipated. We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity under the BPCIA. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. See “Business — Government Regulation — Biosimilars and Reference Product Exclusivity.” Risks Related to Our Dependence on Third Parties The process of manufacturing our **current and future** product candidates is complex and **highly regulated** requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls that are in compliance with cGMP. We do not currently own or operate any cGMP manufacturing facilities, **nor and we do not currently** have any in-house cGMP manufacturing capabilities. **We** **Consequently, we expect to** rely on third-party contract manufacturers to produce sufficient quantities of **materials required for the manufacture, transport, and storage of our compounds** **current and future** product candidates for preclinical testing and clinical trials, in compliance with applicable regulatory and quality standards. **If** **While** we are unable to arrange **have transferred a cGMP manufacturing process** for such **our lead product candidate, SL- 325, to a third-party contract manufacturer, we have not yet completed a cGMP** manufacturing **campaign** sources, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or we may be delayed in doing so. Such failure or substantial delay could materially and adversely harm our business. We currently rely on a limited number of manufacturers for BDS. The loss of one or more of our current manufacturers or their failure to supply us with BDS on a timely basis could result in our inability to develop and manufacture our product candidates, which could materially and adversely affect our business. The process for identifying additional BDS manufacturers and successfully producing BDS with those **the third-party CMO** manufacturers is lengthy and expensive, and there can be no assurance that **a** any additional manufacturers- **manufacturer** will be able to successfully produce satisfactory **BDS product** on a timely basis or at all. **If** we are not able to successfully produce BDS with **With** additional **legacy programs in the past, the** manufacturers- **manufacture**, our existing manufacturers may need to increase manufacturing capacity to meet anticipated demand, which could involve significant challenges. Because we rely on a limited number of **our product candidates by** third-party manufacturers to provide our BDS, there can be no assurance that our supply of BDS will not be limited or interrupted, have satisfactory quality or product characteristics, or continue to be available at acceptable prices. There can also be no assurance that our manufacturers will continue to meet regulatory requirements for cGMP manufacturing. We have experienced enrollment delays in our clinical trials as **was** a result of delays in receipt of BDS. We have limited control over the process or timing of the acquisition or manufacture of materials by our manufacturers. **in** and cannot ensure that they will deliver to us the BDS we order on time, or at all. **In** the normal course of business, the process of manufacturing our product candidates has been negatively impacted by equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. **If** Even minor deviations from normal manufacturing processes, which we **are unable to successfully** have experienced, may result in reduced production yields and other **timely produce sufficient** supply disruptions, including delays in receipt of **our current and future** product candidates for **our planned** clinical trials. **If** microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, this could lead to withdrawal of our products from the market, and such manufacturing facilities may need to be **delayed** closed for an **and materially** extended period of time to investigate and remedy the contamination **adversely harm our business**. As part of our process development efforts, we also may make changes to our manufacturing processes at various points during development for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. We have invested in an in-house process development pilot plant to reduce our reliance on third parties for our process development efforts, however we cannot guarantee that these efforts will result in useful changes to our manufacturing processes. Any changes to our manufacturing processes carry the risk that they will not achieve their intended objectives, and any of

these changes could cause our product ~~candidates-~~ **candidate (s)** to perform differently and affect the results of our ongoing clinical trials or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. ~~We are preparing to scale up to a Phase 3 and commercial manufacturing process, including transferring our manufacturing process to contract development and manufacturing organizations (“CDMOs”), including those that may not yet have completed a cGMP campaign with our product. There is no guarantee that the CDMOs that have produced our clinical trial material to date will be suitable for Phase 3 or commercial manufacturing. Our product candidate has not yet been manufactured on a commercial scale, and there are risks associated with the scaling up of the manufacturing process including, CDMO selection, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, supply chain disruptions and timely availability of raw materials. Even if we obtain regulatory approval for SL-172154, there is no assurance that the manufacturer or manufacturers we have arranged will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand.~~ In addition, the FDA and other regulatory authorities require that our product ~~candidates-~~ **candidate (s)** be manufactured according to cGMPs and similar foreign standards relating to methods, facilities, and controls used in the manufacturing, processing, packing, storage, and distribution of the product, which are intended to ensure that biological products are safe and that they consistently meet applicable requirements and specifications. We are dependent on third parties for all of these activities, and we have limited ability to prevent or control the risk that such activities will not be in compliance with cGMP. In addition, the storage and distribution of our product ~~candidates-~~ **candidate (s)** for use in clinical trials is subject to extensive regulation by the FDA and other regulatory authorities. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product ~~candidates-~~ **candidate (s)** in a timely manner, could lead to a delay in our clinical trials and development efforts, or a delay in or failure to obtain regulatory approval of any of our product ~~candidates-~~ **candidate (s)**. Pharmaceutical manufacturers are also subject to extensive oversight by the FDA and comparable regulatory authorities in other jurisdictions, which include **continual review and** periodic unannounced and announced inspections by the FDA to assess compliance with cGMP requirements. If an FDA inspection of a manufacturer’s facilities reveals conditions that the FDA determines not to comply with applicable regulatory requirements, the FDA may issue observations through a Notice of Inspectional Observations, commonly referred to as a “Form FDA 483” report. If observations in the Form FDA 483 report are not addressed in a timely manner and to the FDA’s satisfaction, the FDA may issue a Warning Letter or proceed directly to other forms of enforcement action. Any failure by one of our contract manufacturers to comply with cGMP or to provide adequate and timely corrective actions in response to deficiencies identified in a regulatory inspection could result in further enforcement action that could lead to a shortage of products and harm our business. The failure of a manufacturer to address any concerns raised by the FDA or foreign regulators could also lead to plant shutdown or the delay or withholding of product approval by the FDA in additional indications, or by foreign regulators in any indication. Moreover, if the FDA determines that our third-party manufacturers are not in compliance with applicable laws and regulations, including those governing cGMPs, the FDA may deny BLA approval until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is in compliance. Certain countries may impose additional requirements on the manufacturing of drug products or drug substances, and on manufacturers, as part of the regulatory approval process for products in such countries. The failure by our third-party manufacturers to satisfy such requirements could impact our ability to obtain or maintain approval of our products in such countries. We rely, and expect to continue to rely, on third parties to conduct preclinical studies, nonclinical studies, and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory authorizations or approvals required to develop or commercialize our product ~~candidates-~~ **candidate (s)** and our business could be materially and adversely affected. We have relied, and plan to continue to rely, upon third parties, including independent clinical investigators and third-party CROs, to help establish and conduct certain preclinical studies, nonclinical studies, and **future** clinical trials and to monitor, record, and manage data for our ongoing preclinical ~~and~~ **nonclinical** ~~programs~~ **and future** clinical programs. We **currently and in the future expect to** rely on these parties for execution of certain preclinical studies and clinical trials, and **we** control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing, and completion of these preclinical studies, nonclinical studies, and clinical trials and the management of data developed through these preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. If we or any of these third parties fail to comply with applicable good laboratory practice, or good clinical practice regulations, such data may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical or nonclinical studies, or clinical trials before approving our marketing applications. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws ~~. The investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, that they devote to our product candidates and clinical trials.~~ There is a limited number of third-party service providers that specialize in or have the expertise required to achieve our business objectives. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or to do so in a timely manner or on commercially reasonable terms. If the third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines; if they need to be replaced; or if the quality or accuracy of the preclinical, nonclinical, or clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements, or for other reasons, our preclinical studies, nonclinical studies, or clinical trials may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product ~~candidates-~~ **candidate (s)**. We may not realize the benefits of any ~~existing or future~~ **collaborative** **collaboration** or licensing arrangement, and if we fail to enter into new strategic relationships our business, financial condition, commercialization prospects, and results of operations may be materially and adversely affected. We have **in the past** entered into, and may decide in the future to enter into, collaborations with pharmaceutical or biopharmaceutical companies ~~, including our collaboration with One,~~ for the development and potential commercialization ~~of certain~~ of our product candidates. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue, or specific net income that justifies such transaction. We may not be able to control the amount and timing of resources that is required of us to complete our development obligations or that the collaboration partner devotes to the product development or marketing programs. We also may not be able to ensure that ~~our any future~~ **collaboration partner** ~~partners~~ **adequately protects-** **protect** ~~and does do~~ not misuse our intellectual property. We and our **future**

collaboration partner ~~partners~~ may disagree regarding the research plan or the development plan for product candidates on which we are collaborating and disputes could arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources. If our strategic collaborations do not result in the successful development and commercialization of product candidates or if one of our collaborators fails to act under the collaboration agreement or terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. ~~For example, if Ono decides not to exercise its option to obtain an exclusive, sublicenseable license to research, develop, manufacture and commercialize products resulting from the Development Compounds under the Ono Agreement, we would not receive any of the potential licensing fees or clinical, regulatory and commercial milestone payments thereunder.~~ In addition, if a collaboration is terminated, it may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. **For example, we were party to collaboration agreements with Takeda and Ono, which were terminated, and will not receive any future funding under those agreements.** If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate such products or business into our existing operations and company culture. If we are unable to obtain sufficient raw and intermediate materials on a timely basis or if we experience other supply difficulties, our business may be materially and adversely affected. We work closely with our suppliers to ensure the continuity of supply of raw and intermediate materials but cannot guarantee these efforts will always be successful. We have experienced, and may continue to experience in the future, raw and intermediate materials supply shortages, which has contributed to manufacturing delays and impacted the progress of our clinical trials. Further, while we work to diversify our sources of raw and intermediate materials, in certain instances we acquire raw and intermediate materials from a sole supplier, and there can be no assurance that we will be able to quickly establish additional or replacement sources for some materials. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our ability to manufacture our product ~~candidates-~~ **candidate (s)** in a timely or cost-effective manner and could delay completion of our **early-stage** clinical trials, product testing, and potential regulatory approval of our product ~~candidates-~~ **candidate (s)**. Risks Related to Intellectual Property and Information Technology Our success depends upon our ability to obtain and maintain patents and other intellectual property rights to protect our technology, including **SL- 325** ~~product candidates from our ARC and platform,~~ methods used to manufacture those product ~~candidates-~~ **candidate (s)**, formulations thereof, and the methods for treating patients using those product ~~candidates-~~ **candidate (s)**. The prosecution, enforcement, defense, and maintenance of intellectual property rights is often challenging, costly, and uncertain. Contributors to these challenges and uncertainty include the early stage of our products and our intellectual property portfolio development; the unpredictability of what patent claim scope will ultimately be issued to protect our products and how the law will change or develop as to scope, length, and enforcement of patent protection; the competitive and crowded **inflammatory and immune autoimmune-** ~~oncology-~~ space; complicated and unforgiving procedural, documentary, and fee requirements of the U. S. PTO, and foreign patent offices; lack of perfect visibility into what our competitors are doing and the patent claim scope they are obtaining; lack of perfect ability to determine what prior art may exist; and the expense and time consuming nature of patent portfolio development across relevant jurisdictions. For at least these reasons, the issuance, scope, validity, enforceability, and commercial value of our current or future patent rights are highly uncertain. We cannot be sure that patent coverage will issue, or will be maintained, to protect our products in some or all relevant jurisdictions. We cannot be sure that we will not encounter freedom- to- operate challenges in the development and commercialization of our product ~~candidates-~~ **candidate (s)**. We cannot be sure our trademarks and trade names are sufficient to build name recognition in our markets of interest. We cannot be sure our measures to protect our trade secrets will be sufficient. Failure to protect or enforce these rights adequately could harm our ability to develop and market our product ~~candidates-~~ **candidate (s)** and could impair our business. Others may challenge our patents or other intellectual property as invalid or unenforceable. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if patents do successfully issue and even if such patents cover our product ~~candidates-~~ **candidate (s)** and extend for a commercially- relevant time, third parties may initiate invalidity, non-infringement, opposition, interference, re- examination, post- grant review, inter partes review, nullification, or derivation actions in court, before patent offices, or similar proceedings challenging the validity, inventorship, ownership, enforceability, or scope of such patents, which may result in the patent claims being narrowed, invalidated, held unenforceable, or circumvented. Such challenges and potential negative results could materially and adversely affect our business. Furthermore, even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention, such as where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. Additionally, some countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties; and some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. Additionally, our competitors or other third parties may be able to evade our patent rights by developing new fusion proteins, antibodies, biosimilar antibodies, or alternative technologies or products in a non- infringing manner. These risks may impact our ability to enjoy the protection we obtain, and may materially and adversely impact our business. Our commercial success depends, in part, on our ability to develop, manufacture, market, and sell our product ~~candidates-~~ **candidate (s)** without infringing or otherwise violating the intellectual property and other proprietary rights of third parties. Others may accuse us of infringing their intellectual property. Contested proceedings are lengthy, time consuming, and costly, and we cannot guarantee that our operations and activities do not, or will not in the future, infringe existing or future patents. We also cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims, or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States and abroad that is relevant to our product ~~candidates-~~ **candidate (s)** or necessary for the commercialization of our product ~~candidates-~~ **candidate (s)** in any jurisdiction. Furthermore, we may be subject to third- party claims asserting that our employees, consultants, contractors, collaborators, or advisors have misappropriated or wrongfully used or disseminated their intellectual property, or claiming ownership of what we regard as our own intellectual property. These and related risks to defending against third- party claims may materially and adversely affect our business. Our competitors in both

the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make, use, and sell our product candidates- **candidate (s)**. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. As such, there may be applications of third parties now pending or recently revived patents of which we are unaware. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates- **candidate (s)**. We may incorrectly determine that our product candidates- **candidate (s)** are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates- **candidate (s)**. We cannot provide any assurances that third- party patents do not exist that might be enforced against our current technology, including our platform technologies, product candidates- **candidate (s)** and their respective methods of use, manufacture, and formulations thereof, and could result in either an injunction prohibiting our manufacture, future sales, or, with respect to our future sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties, which could be significant. We rely, in part, on in- licensed patents and other intellectual property rights to develop and commercialize our product candidates- **candidate (s)**. We may need to obtain additional licenses of third- party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated. Our competitive position may suffer if patents issued to third parties or other third- party intellectual property rights cover our methods or product candidates- **candidate (s)** or elements thereof, our manufacture or uses relevant to our development plans, our product candidates- **candidate (s)** or other attributes of our product candidates- **candidate (s)**, or our compounds, including **SL- 325** those from our ARC platform. In such cases, we may not be in a position to develop or commercialize product candidates- **candidate (s)** unless we successfully pursue litigation to nullify or invalidate the third- party intellectual property right concerned, which can be expensive and time- consuming, or we may have to enter into a license agreement with the intellectual property right holder, which may not be available on commercially reasonable terms, if at all. There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates- **candidate (s)**. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates- **candidate (s)**. For example, we are aware of a patent that may impact our competitive position with respect to **SL- 172154**. The **target** patent lists claims that generally relate to methods of using fusion proteins to treat certain types of cancers. While we believe that the claims may not be valid and that they may be reasonably challenged for validity, there can be no assurance that any such challenge would be successful, in which case we may be required to obtain a license in order to commercialize our product candidate **(s)** has, if approved. The targets of our product candidates have also been the subject of research by many companies that have filed patent applications or have patents related to such targets- **target** and therapeutics methods related to those that targets- **target**. Disputes may arise with our licensors of patents and other intellectual property rights. We may yet need to obtain licenses from others for continued development and commercialization of our product candidates- **candidate (s)**, and we may be unable to secure those licenses on commercially reasonable terms or at all. Should we be required to obtain licenses to any third- party technology, including any such patents required to manufacture, use, or sell our product candidates- **candidate (s)**, the growth of our business will likely depend in part on our ability to acquire, in- license, maintain, or use these proprietary rights. The inability to obtain any third- party license required to develop or commercialize any of our product candidates- **candidate (s)** could cause us to abandon any related efforts, which could seriously harm our business and operations. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to successfully obtain a license to third- party intellectual property rights necessary for the development of a product candidate or program, we may have to abandon development of that product candidate or program and our business and financial condition could suffer. **All** In addition, all licenses impose obligations upon us that must be met to maintain the license. If we are unable to meet these obligations, we may be required to pay damages and our licensors may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we and / or our licensors must cooperate in order to enforce such patents against third parties, and such cooperation may not be provided. We also may rely on our licensors to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property rights we license from them and may have limited control over these activities or any other intellectual property rights that may be related to our in- licensed intellectual property rights. In addition, our competitors may independently develop substantially equivalent trade secrets, proprietary information, or know- how and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and / or confidential know- how. Under certain circumstances, and to make it more likely that we have our freedom to operate, we may also decide to publish some know- how to make it difficult for others to obtain patent rights covering such know- how, at the risk of potentially exposing our trade secrets to our competitors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. We **may** depend on intellectual property licensed from third parties and if we fail to comply with our obligations under any license, ~~collaboration~~ or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates- **candidate (s)** or we could lose certain rights to grant sublicenses. Our current licenses impose, and any future licenses we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement, and / or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell any future products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor' s rights. In addition, while we cannot determine currently the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future

royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability. We **may** enjoy only limited geographical protection with respect to certain patents and may not be able to protect our intellectual property rights throughout the world. Patents are of national or regional effect. While we will endeavor to try to protect our technologies, products and product candidates with intellectual property rights such as patents throughout the world, as appropriate, the process of obtaining patents is time- consuming, expensive, and sometimes unpredictable in other countries. In addition, differences in patent laws throughout the world may make it difficult to obtain uniform patent coverage in the jurisdictions where we have patent protection. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all markets. We have not, and will not, file for patent protection in all national and regional jurisdictions where such protection may be available. Filing, prosecuting, and defending patents on all of our research programs, compounds, and product candidates in all countries throughout the world would be prohibitively expensive, and, therefore, the scope and strength of our intellectual property rights will vary from jurisdiction to jurisdiction. Changes in patent laws in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. Changes in either the patent laws or interpretation of the patent laws in the United States or in foreign jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The patent laws of the U. S. and foreign jurisdictions, as well as the rules of the U. S. PTO and foreign patent offices, change from time to time. Further changes to the patent laws and / or rules of the U. S. PTO and foreign patent offices may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. The Supreme Court and other federal courts also regularly rule on patent cases, including those involving the life sciences. Those decisions can change the interpretation of patent laws; for example, narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. These changes to patent laws and subsequent court decisions related to patent rights have created uncertainty with respect to the value of patents once obtained. Depending on decisions by Congress, the federal courts and the U. S. PTO, and similar legislative and regulatory bodies in other countries in which we may pursue patent protection, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative: • others may be able to make product candidates similar to our product ~~candidates~~ **candidate (s)** but that are not covered by the claims of the patents that we own or have exclusively licensed; • the patents of third parties may have a material and adverse effect on our business; • we or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed; • we or any future strategic partners might not have been the first to file patent applications covering certain of our inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating, or otherwise violating our intellectual property rights; • our pending patent applications might not lead to issued patents; • issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; • we cannot predict the degree and range of protection any issued patents will afford us against competitors, whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications, or whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • third parties performing manufacturing or testing for us using our product ~~candidates~~ **candidate (s)** or technologies could use the intellectual property of others without obtaining a proper license; and • we may not develop additional technologies that are patentable. Should any of these events occur, they could significantly harm our business, results of operations, and prospects. We rely on trade secret and proprietary know- how, which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Trade secrets and / or proprietary know- how can be difficult to protect or maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, we generally require our employees, consultants, contractors, collaborators, advisors, and other third parties to enter into confidentiality agreements with us. Despite these efforts, any of these parties may unintentionally or willfully breach the agreements and disclose our confidential information, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Enforcing a claim that a third party illegally obtained and is using trade secrets and / or confidential know- how is also expensive, time- consuming, and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, some courts inside and outside the

United States are less willing or are unwilling to protect trade secrets or other proprietary information. Any sort of contested proceeding related to intellectual property, whether offensive or defensive, may cause us to incur significant expenses and would be likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities, and may impact our reputation. There could be public announcements of the results of or developments in hearings, motions or other interim proceedings and if securities analysts or investors perceive these results or developments to be negative, it could have a material and adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Infringement or related suits against us by others could result in damages awards against us or injunction or other equitable relief precluding continued commercialization of our products. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements. Periodic maintenance and annuity fees on any issued patent are due to be paid to the U. S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U. S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process and in order to maintain the patent once issued. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents within prescribed time limits. If we fail to maintain the patents and patent applications covering our product candidates- **candidate (s)** or if we otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would have a material and adverse effect on our business. Our information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches, which could materially and adversely affect our business. In the ordinary course of our business, we collect, store, and transmit large amounts of confidential information in digital form. Despite the implementation of security measures, our information technology systems and data, and those of our current or future CROs or other contractors and consultants, are vulnerable to compromise or damage from computer hacking, malicious software, fraudulent activity, employee misconduct, human error, telecommunication and electrical failures, natural disasters, or other cybersecurity attacks or accidents. While we continue to make investments to improve the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Although, to our knowledge, we have not experienced any material cybersecurity incident to date, if such an event were to occur, it could seriously harm our development programs and our business operations or subject us to litigation or regulatory actions taken by governmental authorities. See **the sections titled Part I, Item 1.** “ Business — Government Regulation — Data Privacy and Security ” and **Part I, item 1C.** “ Cybersecurity. ” Further, a cybersecurity incident may disrupt our business or damage our reputation, which could have a material adverse effect on our business, prospects, operating results, share price, stockholder value, and financial condition. We could also incur substantial remediation costs, including the costs of investigating the incident, repairing or replacing damaged systems, restoring normal business operations, implementing increased cybersecurity protections, and paying increased insurance premiums. In addition, because we collect, store and transmit confidential information in digital form, we, and third parties who we work with, are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. We are or may become subject to the terms of contractual obligations related to privacy, data protection, and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations. See the section titled “ Business — Government Regulation — Data Privacy and Security ” for a more detailed description of the laws that may affect our ability to operate. Risks Related to Ownership of Our Common Stock Our stock price may be volatile or may decline regardless of our operating performance, resulting in substantial losses for investors. The market price of our common stock may be highly volatile and may fluctuate significantly as a result of a variety of factors, some of which are related in complex ways and many of which are beyond our control, including the factors described in this “ Risk Factors ” section and elsewhere in this Annual Report on Form 10- K. In addition, the stock market in general, and The Nasdaq Stock Market — and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’ s securities. We have in the past been subject to securities class action litigation following periods of volatility in the market price of our securities. While this litigation was settled, if any similar litigation was instituted in the future, it could result in substantial costs and a diversion of management’ s attention and resources, which would harm our business, operating results, or financial condition. See the discussion of Legal Proceedings in Part I, Item 3 of this Form 10- K. Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval. As of **February 1 March 27, 2024-2025**, our executive officers, directors, holders of 5 % or more of our capital stock and their respective affiliates beneficially owned a significant percentage of our outstanding common stock. Therefore, these stockholders have the ability to influence us through this ownership position and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline. We cannot predict what effect, if any, sales of our shares in the

public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares sold through our ATM Facility or shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, could adversely affect the market price of our common stock. We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Because we do not anticipate paying any dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and do not anticipate declaring or paying any dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. General Risk Factors Our business could be adversely affected by economic downturns, inflation, **fluctuating increases in interest rates, changes in trade policies, including tariffs or other trade restrictions or the threat of such actions**, natural disasters, public health crises, such as pandemics, political crises, geopolitical events, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, **increases in fluctuating interest and inflation rates, higher interest rates changes in trade policies, including tariffs or other trade restrictions or the threat of such action**, and uncertainty about economic stability. For example, **higher fluctuating** interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending, and ongoing military conflicts throughout the world have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. We have experienced and may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition. Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our business, financial condition or results of operations. Our cash held in non-interest-bearing and interest-bearing accounts exceeds the Federal Deposit Insurance Corporation (“FDIC”) insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. **For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole. However, the** FDIC may not make all account holders whole in the event of **future** bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders’ access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business. If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the trading price or trading volume of our common stock could decline. The trading market for our common stock depends in part upon research and reports that securities or industry analysts may publish about us, our business, our market, or our competitors. **If As we have experienced in the past, if** any analyst who may cover us **in the future** were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline. In addition, the price of our common stock could decline if one or more analysts downgrade our stock or issue **inaccurate or** other unfavorable commentary or research. The requirements of being a public company may strain our resources, result in litigation, and divert management’s attention. As a public company, we are subject to certain reporting requirements, listing requirements, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. As a result, management’s attention may be diverted from other business concerns, which could materially and adversely affect our business and operating results. **In We will no longer qualify as an “emerging growth company” as of January 1, 2026, and will consequently have increased reporting obligations beginning with our Annual Report on Form 10-K for the year ended December 31, 2025. Any addition-additional**, a change in our filer status could trigger a requirement to begin complying with Section 404 (b) of the Sarbanes-Oxley Act of 2002, and our independent registered public accounting firm would have to evaluate and report on the effectiveness of internal control over financial reporting, increasing our costs. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses. By disclosing information in this and in future filings required of a public company, our business and financial condition will become more visible, which has resulted in, and may in the future result in, threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management’s resources and seriously harm our business. Litigation filed against us could harm our business, and insurance coverage may not be sufficient to cover all related costs and damages. We face the threat of legal claims and regulatory matters involving various aspects of our business. Given the volatility of the trading price of our common stock, and the prevalence of shareholder litigation generally, we face a risk of lawsuits alleging violations of the securities laws. Litigation is inherently uncertain, and adverse rulings may occur, including awards of monetary damages, that may have a material adverse impact on our business. These lawsuits may also divert management’s attention and resources, and may require us to incur substantial costs, some of which will not be covered by insurance. We may become exposed to costly and damaging liability claims, either when testing **our a product candidates- candidate (s)** in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims. We are exposed to potential product liability and professional indemnity risks

that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the ~~current and~~ future use of ~~our a~~ product ~~candidates-~~ **candidate (s)** in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims may be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially and adversely affect the market for our product ~~candidates-~~ **candidate (s)** or any prospects for commercialization of our product ~~candidates-~~ **candidate (s)**. Although we currently maintain adequate product liability insurance for our product ~~candidates-~~ **candidate (s)**, it is possible that ~~our any~~ liabilities could exceed our insurance coverage or that in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired. We are required to report upon the effectiveness of our internal control over financial reporting. To comply with the requirements of being a reporting company under the Exchange Act, we have implemented and will continue to implement additional financial and management controls, reporting systems, and procedures and we have hired and will continue to hire additional accounting and finance staff. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Exchange Act. We have designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and Delaware law might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock. Our amended and restated certificate of incorporation and our amended and restated bylaws each contain provisions that could depress the market price of our common stock by acting to discourage, delay, or prevent a change in control of the Company or changes in our management that the stockholders of the Company may deem advantageous. As a Delaware corporation, we are subject to the anti- takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in a business combination specified in the statute with an interested stockholder (as defined in the statute) for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in advance by a majority of the independent directors or by the holders of at least two- thirds of the outstanding disinterested shares. The application of Section 203 of the Delaware General Corporation Law could also have the effect of delaying or preventing a change of control of the Company. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction) is the exclusive forum for certain actions. It also provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act. These exclusive forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes, which may discourage lawsuits. In addition, there is uncertainty as to whether a court would enforce such provisions. If a court were to find these types of provisions to be inapplicable or unenforceable, and if a court were to find the exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could materially and adversely affect our business. Our ability to use our net operating loss carryforwards and other tax attributes may be limited. As of December 31, ~~2023-~~ **2024**, we had U. S. federal and state net operating loss (" NOL "), carryforwards of \$ ~~149-~~ **195** . ~~5-~~ **8** million, which may be available to offset future taxable income. As of December 31, ~~2023-~~ **2024**, we also had gross federal tax credits of \$ ~~16-~~ **21** . ~~9-~~ **6** million, which may be used to offset future tax liabilities. These NOLs and tax credit carryforwards ~~will begin~~ **began** to expire in 2024. Use of our NOL carryforwards and tax credit carryforwards depends on many factors, including having current or future taxable income, which cannot be assured.