Risk Factors Comparison 2025-02-26 to 2024-02-07 Form: 10-K

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You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report on Form 10- K and in our other public filings in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline. Risk Factor Summary Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading " Risk Factors " and should be carefully considered, together with other information in this Annual Report on Form 10- K and our other filings with the Securities and Exchange Commission, or the SEC, before making an investment decision regarding our common stock. • We are a clinical-stage company, have a ~~very~~ limited operating history and are expected to incur significant operating losses during the next stages of our corporate development. • We are substantially dependent on technologies we licensed from Ligand Pharmaceuticals Incorporated, or Ligand, and if we lose the license to such technologies or our master license agreement with Ligand, or the Master License Agreement, is terminated for any reason, our ability to develop existing and new drug candidates would be harmed, and our business, financial condition and results of operations would be materially and adversely affected. • We are dependent on the success of one or more of our current drug candidates and we cannot be certain that any of them will receive regulatory approval or be commercialized. • If development of our drug candidates does not produce favorable results, we and our collaborators, if any, may be unable to commercialize these products. • Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations. • We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business, financial condition and results of operations could be substantially harmed. • If our competitors have drug candidates that are approved faster, are marketed more effectively, are better tolerated, have a more favorable safety profile or are demonstrated to be more effective than ours, our commercial opportunity may be reduced or eliminated. • Unstable market and economic conditions may have serious adverse consequences on our business and financial condition. • We may not be successful in obtaining or maintaining necessary rights to our drug candidates through acquisitions and in- licenses. • If we fail to comply with our obligations in the agreements under which we in- license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business. Risks Relating to Our Business We are a clinical- stage company. Since our incorporation in September 2012, our operations have been limited to raising capital, building infrastructure, obtaining the worldwide rights to certain technology from Ligand Pharmaceuticals Incorporated, or Ligand, and planning, preparing and conducting preclinical studies and clinical trials of our drug candidates, including ~~VK2809,~~ VK2735 subcutaneous **, VK2735 oral, VK2809** , VK5211 and VK0612, which are currently in Phase 2 clinical development, ~~VK2735, currently in an oral Phase 1 SAD / MAD clinical trial, and~~ VK0214, ~~currently in~~ **for which we recently completed** a Phase 1b clinical trial, as well as the **dual amylin and calcitonin receptor agonist, or DACRA,** diacylglycerol acyltransferase- 1, or DGAT- 1 and erythropoietin receptor, or EPOR, programs, which are each currently in preclinical development. We have not yet demonstrated an ability to obtain marketing approval for any of our drug candidates or successfully overcome the risks and uncertainties frequently encountered by companies in the biopharmaceutical industry. We also have not generated any revenue to date, and we continue to incur significant research and development and other expenses. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~377~~ **487** . 9 million. For the foreseeable future, we expect to continue to incur losses, which will increase significantly from historical levels as we expand our drug development activities, seek potential partnering opportunities and / or regulatory approvals for our drug candidates and begin to commercialize them if they are approved by the U. S. Food and Drug Administration, or the FDA, the European Medicines Agency, or EMA, or comparable foreign authorities. Even if we succeed in partnering or developing and commercializing one or more drug candidates, we may never become profitable. If we fail to achieve or maintain profitability, it would adversely affect the value of our common stock ~~. We are substantially dependent on technologies we licensed from Ligand Pharmaceuticals Incorporated, or Ligand, and if we lose the license to such technologies or our master license agreement with Ligand, or the Master License Agreement, is terminated for any reason, our ability to develop existing and new drug candidates would be harmed, and our business, financial condition and results of operations would be materially and adversely affected~~ . Our business is substantially dependent upon technology licensed from Ligand. Pursuant to the Master License Agreement, we have been granted exclusive worldwide rights to VK2809, VK0214, VK5211, VK0612 and preclinical programs for metabolic disorders and anemia. Selective androgen receptor modulators, such as the one used in our VK5211 program, are key compounds used by us in the development and commercialization of our drug candidates. Most of the intellectual property related to our drug candidates is currently owned by Ligand, and we have the rights to use such intellectual property pursuant to the Master License Agreement. Therefore, our ability to develop and commercialize **certain of** our drug candidates depends entirely on the effectiveness and continuation of the Master License Agreement. If we lose the right to license any of these key compounds, our ability to develop existing and new drug candidates would be harmed. Ligand has the right to terminate the Master License Agreement under certain circumstances, including, but not limited to: (1) in the event of our insolvency or bankruptcy, (2) if we do not pay an

undisputed amount owing under the Master License Agreement when due and fail to cure such default within a specified period of time, or (3) if we default on certain of our material obligations and fail to cure the default within a specified period of time. We have spent significant time, money and effort on the licensing and development of our core metabolic and endocrine disease assets, **VK2735 subcutaneous, VK2735 oral,** VK2809 ~~, VK2735~~, VK0214, VK5211, VK0612 and our earlier- stage assets, our **DACRA,** DGAT- 1 and EPOR programs. To date, no pivotal clinical trials designed to provide clinically and statistically significant proof of efficacy, or to provide sufficient evidence of safety to justify approval, have been completed with any of our drug candidates. All of our drug candidates will require additional development, including clinical trials as well as further preclinical studies to evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation, and regulatory clearances before they can be commercialized. Positive results obtained during early development do not necessarily mean later development will succeed or that regulatory clearances will be obtained. Our drug development efforts may not lead to commercial drugs, either because our drug candidates fail to be safe and effective or because we have inadequate financial or other resources to advance our drug candidates through the clinical development and approval processes. If any of our drug candidates fail to demonstrate safety or efficacy at any time or during any phase of development, we would experience potentially significant delays in, or be required to abandon, development of the drug candidate. We do not anticipate that any of our current drug candidates will be eligible to receive regulatory approval from the FDA, EMA or comparable foreign authorities and begin commercialization for a number of years, if ever. Even if we ultimately receive regulatory approval for any of these drug candidates, we or our potential future partners, if any, may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost- effectiveness, the cost of manufacturing the product on a commercial scale and competition with other drugs. The success of our drug candidates may also be limited by the prevalence and severity of any adverse side effects. If we fail to commercialize one or more of our current drug candidates, we may be unable to generate sufficient revenues to attain or maintain profitability, and our financial condition and stock price may decline. To receive regulatory approval for the commercialization of our core metabolic and endocrine disease assets, **VK2735 subcutaneous, VK2735 oral,** VK2809 ~~, VK2735~~, VK0214, VK5211, VK0612 and our earlier- stage assets, our **DACRA,** DGAT- 1 and EPOR programs, or any other drug candidates that we may develop, adequate and well-controlled clinical trials must be conducted to demonstrate safety and efficacy in humans to the satisfaction of the FDA, EMA and comparable foreign authorities. In order to support marketing approval, these agencies typically require successful results in one or more Phase 3 clinical trials, which our current drug candidates have not yet reached and may never reach. The development process is expensive, can take many years and has an uncertain outcome. Failure can occur at any stage of the process. We may experience numerous unforeseen events during, or as a result of, the development process that could delay or prevent commercialization of our current or future drug candidates, including the following: • clinical trials may produce negative or inconclusive results; • preclinical studies conducted with drug candidates during clinical development to, among other things, evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation may produce unfavorable results; • patient recruitment and enrollment in clinical trials may be slower than we anticipate; • costs of development may be greater than we anticipate; • our drug candidates may cause undesirable side effects that delay or preclude regulatory approval or limit their commercial use or market acceptance, if approved; • collaborators who may be responsible for the development of our drug candidates may not devote sufficient resources to these clinical trials or other preclinical studies of these candidates or conduct them in a timely manner; or • we may face delays in obtaining regulatory approvals to commence one or more clinical trials. Success in early development does not mean that later development will be successful because, for example, drug candidates in later- stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical trials. ~~We licensed most of the intellectual property related to our current drug candidates from Ligand pursuant to the Master License Agreement.~~ In ~~May~~ **February** ~~2023~~ **2024** , we reported positive top- line results from the **VENTURE Phase 2 clinical trial for VK2735 in patients with obesity, and we plan to advance the subcutaneous formulation of VK2735 into Phase 3 development. In May 2023, we reported positive top- line results from the** VOYAGE Phase 2b clinical trial for VK2809 **and in June 2024, we announced positive 52- week histologic data from the VOYAGE study** . In late 2017, we reported positive top- line results from a Phase 2 clinical trial for VK5211. **In October 2024, we reported positive data from our Phase 1b clinical trial of VK0214 in patients with X- ALD.** However, there is no guarantee that the results of our Phase 2 clinical trials for **VK2735 subcutaneous or** VK2809 or ~~VK5211~~ **our Phase 1b clinical trial for VK2014** will be repeated for our other drug candidates or lead to other positive outcomes **, including any Phase 3 trials** . As a company, we have conducted only a limited number of clinical trials and preclinical studies for our drug candidates. Therefore, we have limited experience in conducting clinical trials for our drug candidates. Since our experience with our drug candidates is limited, we will need to train our existing personnel and hire additional personnel in order to successfully administer and manage our clinical trials and other studies as planned, which may result in delays in completing such planned clinical trials and preclinical studies. Moreover, to date, our drug candidates have been tested in less than the number of patients that will likely need to be studied to obtain regulatory approval. The data collected from clinical trials with larger patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of these drug candidates. We currently do not have strategic collaborations in place for clinical development of any of our current drug candidates. Therefore, in the future, we or any potential future collaborative partner will be responsible for establishing the targeted endpoints and goals for development of our drug candidates. These targeted endpoints and goals may be inadequate to demonstrate the safety and efficacy levels required for regulatory approvals. Even if we believe data collected during the development of our drug candidates are promising, such data may not be sufficient to support marketing approval by the FDA, EMA or comparable foreign authorities. Further, data generated during development can be interpreted in different ways, and the FDA, EMA or comparable foreign authorities may interpret such data in different ways than us or our collaborators. Our failure to adequately demonstrate the safety and efficacy of our drug candidates would prevent our receipt of regulatory approval, and ultimately the potential

commercialization of these drug candidates. Since we do not currently possess the resources necessary to independently develop and commercialize the majority of our drug candidates, we may seek to enter into collaborative agreements to assist in the development and potential future commercialization of some or all of these assets as a component of our strategic plan. However, our discussions with potential collaborators may not lead to the establishment of collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations, leading to development and potential commercialization delays, which would adversely affect our business, financial condition and results of operations. We expect to continue to incur significant research and development expenses, which may make it difficult for us to attain profitability. We expect to expend substantial funds in research and development, including preclinical studies and clinical trials of our drug candidates, and to manufacture and market any drug candidates in the event they are approved for commercial sale. We also may need additional funding to develop or acquire complementary companies, technologies and assets, as well as for working capital requirements and other operating and general corporate purposes. Moreover, our planned increases in staffing will dramatically increase our costs in the near and long- term. However, our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable products. Due to our limited financial and managerial resources, we must focus on a limited number of research programs and drug candidates and on specific indications. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Because the successful development of our drug candidates is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them. In addition, we may not be able to generate sufficient revenue, even if we are able to commercialize any of our drug candidates, to become profitable. Given our lack of current cash inflows, it is expected that we may need to raise additional capital; however, it may be unavailable to us or, even if capital is obtained, may cause dilution or place significant restrictions on our ability to operate our business. Since we will be unable to generate sufficient, if any, cash inflows to fund our operations for the foreseeable future, we may need to seek additional equity or debt financing to provide the capital required to maintain or expand our operations. As of December 31, ~~2023~~ **2024** , we had cash, cash equivalents and investments totaling $ ~~362~~ **902** . ~~1~~ **6** million. There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations may be materially adversely affected. In addition, we may be required to grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves. Our inability to fund our business could lead to the loss of your investment. Our future capital requirements will depend on many factors, including, but not limited to: • the scope, rate of progress, results and cost of our clinical trials, preclinical studies and other related activities; • our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements; • the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future drug candidates; • the number and characteristics of the drug candidates we seek to develop or commercialize; • the cost of manufacturing clinical supplies, and establishing commercial supplies, of our drug candidates; • the cost of commercialization activities if any of our current or future drug candidates are approved for sale, including marketing, sales and distribution costs; • the expenses needed to attract and retain skilled personnel; • the costs associated with being a public company; • the amount of revenue, if any, received from commercial sales of our drug candidates, should any of our drug candidates receive marketing approval; and • the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation. On July 26, 2023, we filed an automatic universal shelf registration statement on Form S- 3 (File No. 333- 273460) with the SEC as a well- known seasoned issuer as defined in Rule 405 under the Securities Act of 1933, as amended, which became effective upon filing, or the 2023 Shelf Registration Statement. The 2023 Shelf Registration Statement allows us to offer an indeterminate amount of securities, including equity securities, debt securities, warrants, rights, units and depositary shares, from time to time as described in the 2023 Shelf Registration Statement. The specific terms of any offering under the 2023 Shelf Registration Statement will be established at the time of such offering under a separate prospectus supplement, which will be filed with the SEC at the time of any offering. The 2023 Shelf Registration Statement will expire on July 26, 2026. The 2023 Shelf Registration Statement includes a prospectus, or the ATM Prospectus, pursuant to which we may offer and sell, from time to time, through or to Stifel, Nicolaus & Company, Incorporated, Truist Securities, Inc., H. C. Wainwright & Co. LLC and BTIG, LLC, or, collectively, the ATM Agents, as sales agent (s) or principal (s), shares of our common stock having an aggregate offering price of up to $ 200. 0 million, or the ATM Offering. Any shares offering and sold in ATM Offering will be issued pursuant to the ATM Prospectus and the At- The-Market Equity Offering Sales Agreement, dated July 28, 2021, as amended on July 26, 2023, among us and the ATM Agents **. As of December 31, 2024, we may sell shares of our common stock for remaining gross proceeds of up to $ 151. 9 million from time to time pursuant to the ATM Prospectus. On March 4, 2024, we completed an underwritten public offering of our common stock, or the March 2024 Offering, pursuant to the 2023 Shelf Registration Statement. In the March 2024 Offering, we sold an aggregate of 7, 441, 650 shares of our common stock at a public offering price of $ 85. 00 per share, which included the exercise in full by the underwriters of their option to purchase 970, 650 additional shares of common stock. Of the shares sold, 2, 193, 251 were issued out of our treasury shares. Upon the closing of the March 2024 Offering, we received net proceeds of $ 597. 1 million, after deducting underwriting discounts, commissions and other offering expenses** . If we raise additional capital by issuing equity securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock. Given our need for cash and that equity issuances are the most common type of fundraising for companies like ours, the risk of dilution is particularly significant for stockholders of our company. Our drug candidates may cause undesirable side effects that could delay or prevent

their regulatory approval or commercialization or have other significant adverse implications on our business, financial condition and results of operations. Undesirable side effects observed in clinical trials or in supportive preclinical studies with our drug candidates could interrupt, delay or halt their development and could result in the denial of regulatory approval by the FDA, EMA or comparable foreign authorities for any or all targeted indications or adversely affect the marketability of any such drug candidates that receive regulatory approval. In turn, this could eliminate or limit our ability to commercialize our drug candidates. Our drug candidates may exhibit adverse effects in preclinical toxicology studies and adverse interactions with other drugs. There are also risks associated with additional requirements the FDA, EMA or comparable foreign authorities may impose for marketing approval with regard to a particular disease. Our drug candidates may require a risk management program that could include patient and healthcare provider education, usage guidelines, appropriate promotional activities, a post-marketing observational study, and ongoing safety and reporting mechanisms, among other requirements. Prescribing could be limited to physician specialists or physicians trained in the use of the drug, or could be limited to a more restricted patient population. Any risk management program required for approval of our drug candidates could potentially have an adverse effect on our business, financial condition and results of operations. Undesirable side effects involving our drug candidates may have other significant adverse implications on our business, financial condition and results of operations. For example: • we may be unable to obtain additional financing on acceptable terms, if at all; • our collaborators may terminate any development agreements covering these drug candidates; • if any development agreements are terminated, we may determine not to further develop the affected drug candidates due to resource constraints and may not be able to establish additional collaborations for their further development on acceptable terms, if at all; • if we were to later continue the development of these drug candidates and receive regulatory approval, earlier findings may significantly limit their marketability and thus significantly lower our potential future revenues from their commercialization; • we may be subject to product liability or stockholder litigation; and • we may be unable to attract and retain key employees. In addition, if any of our drug candidates receive marketing approval and we or others later identify undesirable side effects caused by the product: • regulatory authorities may withdraw their approval of the product, or we or our partners may decide to cease marketing and sale of the product voluntarily; • we may be required to change the way the product is administered, conduct additional clinical trials or preclinical studies regarding the product, change the labeling of the product, or change the product' s manufacturing facilities; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from the sale of the product. Our efforts to discover drug candidates beyond our current drug candidates may not succeed, and any drug candidates we recommend for clinical development may not actually begin clinical trials. We intend to continue to use our technology, including our licensed technology, knowledge and expertise to develop novel drugs to address some of the world' s most widespread and costly chronic diseases. We intend to expand our existing pipeline of core assets by advancing drug compounds from current ongoing discovery programs into clinical development. However, the process of researching and discovering drug compounds is expensive, time- consuming and unpredictable. Data from our current preclinical programs may not support the clinical development of our lead compounds or other compounds from these programs, and we may not identify any additional drug compounds suitable for recommendation for clinical development. Moreover, any drug compounds we recommend for clinical development may not demonstrate, through preclinical studies, indications of safety and potential efficacy that would support advancement into clinical trials. Such findings would potentially impede our ability to maintain or expand our clinical development pipeline. Our ability to identify new drug compounds and advance them into clinical development also depends upon our ability to fund our research and development operations, and we cannot be certain that additional funding will be available on acceptable terms, or at all. We may expend our limited resources to pursue a specific product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future discovery and preclinical development programs and product candidates for specific indications may not yield any commercially viable products. In addition, our projections of both the number of people who have the targeted indications, as well as the subset of people with these disorders who have the potential to benefit from treatment with our product candidates, are based on estimates. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business. Additionally, the potentially addressable patient population for our product candidates may be limited, or may not be amenable to treatment with our product candidates. Delays in the commencement or completion of clinical trials could significantly impact our drug development costs. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including, but not limited to, delays related to: • obtaining regulatory approval to commence one or more clinical trials; • reaching agreement on acceptable terms with prospective CROs and clinical trial sites; • manufacturing sufficient quantities of a drug candidate or other materials necessary to conduct clinical trials, as well as receiving the supplies and materials needed to conduct our clinical trials, including interruptions in global shipping that may affect the transport of clinical materials; • obtaining institutional review board approval to conduct one or more clinical trials at a prospective site; • recruiting and enrolling patients to participate in one or more clinical trials, especially as patients may be reluctant or unable to visit clinical sites, or may delay seeking treatment for chronic conditions; • the failure of our collaborators to adequately resource our drug candidates due to their focus on other programs or as a result of general market conditions; • recruiting clinical site investigators, clinical site staff and potential closure of clinical facilities; and • changes in regulations, which may require us to change the ways in which our clinical trials are conducted. In

addition, once a clinical trial has begun, it may be suspended or terminated by us, our collaborators, the institutional review boards or data safety monitoring boards charged with overseeing our clinical trials, the FDA, EMA or comparable foreign authorities due to a number of factors, including: • failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols; • inspection of the clinical trial operations or clinical trial site by the FDA, EMA or comparable foreign authorities resulting in the imposition of a clinical hold; • unforeseen safety issues; or • lack of adequate funding to continue the clinical trial. If we experience delays in the completion or termination of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to commence product sales and generate product revenues from any of our product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process. Delays in completing our clinical trials could also allow our competitors to obtain marketing approval before we do or shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Results of earlier clinical trials may not be predictive of the results of later- stage clinical trials. The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons. This drug candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical to early to late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late stage clinical trials, approval and commercialization, such changes carry the risk that they will not achieve these intended objectives. Any of these changes could make the results of our planned clinical trials or other future clinical trials we may initiate less predictable and could cause our product candidates to perform differently, including causing toxicities, which could delay completion of our clinical trials, delay approval of our product candidates and / or jeopardize our ability to commence product sales and generate revenues. If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. For example, the COVID- 19 pandemic previously negatively impacted our ability to recruit and enroll patients for our clinical trials, as they may ~~be~~ **have been** reluctant or unable to visit clinical sites, or may **have** ~~delay~~ **delayed** seeking treatment for chronic conditions. If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the product candidate being tested in such clinical trial is safe and effective. Additionally, enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. We have relied upon and plan to continue to rely upon third- party CROs, medical institutions, clinical investigators and contract laboratories to monitor and manage data for our licensed ongoing preclinical and clinical programs. Nevertheless, we maintain responsibility for ensuring that each of our clinical trials and preclinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with current requirements on good manufacturing practices, or cGMP, good clinical practices, or GCP, and good laboratory practice, or GLP, which are a collection of laws and regulations enforced by the FDA, EMA or comparable foreign authorities for all of our drug candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of preclinical study and clinical trial sponsors, principal investigators, preclinical study and clinical trial sites, and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign authorities may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced consistent with cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the development and regulatory approval processes. If any of our relationships with these third- party CROs, medical institutions, clinical investigators or contract laboratories terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the

quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. CROs may also generate higher costs than anticipated. As a result, our business, financial condition, results of operations and the commercial prospects for our drug candidates could be materially and adversely affected, our costs could increase and our ability to generate revenue could be delayed. Switching or adding additional CROs, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management' s time and focus. In addition, there is a natural transition period when a new CRO commences work replacing a previous CRO. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition or results of operations. In addition, our CROs may need to make certain adjustments to the operation of our trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA on March 18, 2020 and generally, and may need to make further adjustments in the future. Many of these adjustments are new and untested, may not be effective, and may have unforeseen effects on the enrollment, progress and completion of these trials and the findings from these trials. Our drug candidates are subject to extensive regulation under the FDA, EMA or comparable foreign authorities, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our drug candidates. The clinical development, manufacturing, labeling, storage, record- keeping, advertising, promotion, export, marketing and distribution of our drug candidates are subject to extensive regulation by the FDA and other U. S. regulatory agencies, EMA or comparable authorities in foreign markets. In the U. S., neither we nor our collaborators are permitted to market our drug candidates until we or our collaborators receive approval of a new drug application, or an NDA, from the FDA or receive similar approvals abroad. The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the drug candidates involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products, making it more difficult for us to achieve such approval in a timely manner or at all. For example, the FDA has released draft guidance regarding clinical trials for drug candidates treating diabetes that may result in more stringent requirements for the clinical trials and regulatory approval of such drug candidates. This and any future guidance that may result from recent FDA advisory panel discussions on the topic of diabetes, non- alcoholic steatohepatitis, or NASH **/ MASH** , and other metabolic indications, may make it more expensive to develop and commercialize such drug candidates for such indications. Such increased expense could make it more difficult to obtain favorable terms in the collaborative arrangements we require to maximize the value of our programs seeking to develop new drug candidates for diabetes. In addition, as a company, we have not previously filed NDAs with the FDA or filed similar applications with other foreign regulatory agencies. This lack of experience may impede our ability to obtain FDA or other foreign regulatory agency approval in a timely manner, if at all, for our drug candidates for which development and commercialization is our responsibility. Despite the time and expense invested, regulatory approval is never guaranteed. The FDA, EMA or comparable foreign authorities can delay, limit or deny approval of a drug candidate for many reasons, including: • a drug candidate may not be deemed safe or effective; • agency officials of the FDA, EMA or comparable foreign authorities may not find the data from non- clinical or preclinical studies and clinical trials generated during development to be sufficient; • the FDA, EMA or comparable foreign authorities may not approve our third- party manufacturers' processes or facilities; or • the FDA, EMA or a comparable foreign authority may change its approval policies or adopt new regulations. Our inability to obtain these approvals would prevent us from commercializing our drug candidates. Even if our drug candidates receive regulatory approval in the U. S., we may never receive approval or commercialize our products outside of the U. S. In order to market any products outside of the U. S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U. S. as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay seeking or obtaining such approval would impair our ability to develop foreign markets for our drug candidates. Even if any of our drug candidates receive regulatory approval, our drug candidates may still face future development and regulatory difficulties. If any of our drug candidates receive regulatory approval, the FDA, EMA or comparable foreign authorities may still impose significant restrictions on the indicated uses or marketing of the drug candidates or impose ongoing requirements for potentially costly post- approval studies and trials. In addition, regulatory agencies subject a product, its manufacturer and the manufacturer' s facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, our collaborators or us, including requiring withdrawal of the product from the market. Our drug candidates will also be subject to ongoing FDA, EMA or comparable foreign authorities' requirements for the labeling, packaging, storage, advertising, promotion, record- keeping and submission of safety and other post- market information on the drug. If our drug candidates fail to comply with applicable regulatory requirements, a regulatory agency may: • issue warning letters or other notices of possible violations; • impose civil or criminal penalties or fines or seek disgorgement of revenue or profits; • suspend any ongoing clinical trials; • refuse to approve pending applications or supplements to approved applications filed by us or our collaborators; • withdraw any regulatory approvals; • impose restrictions on operations, including costly new manufacturing requirements, or shut down our manufacturing

operations; or • seize or detain products or require a product recall. The FDA, EMA and comparable foreign authorities actively enforce the laws and regulations prohibiting the promotion of off- label uses. The FDA, EMA and comparable foreign authorities strictly regulate the promotional claims that may be made about prescription products, such as our drug candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA, EMA or comparable foreign authorities as reflected in the product' s approved labeling. If we receive marketing approval for our drug candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment that our products could be used in such manner. However, if we are found to have promoted our products for any off- label uses, the federal government could levy civil, criminal or administrative penalties, and seek fines against us. Such enforcement has become more common in the industry. The FDA, EMA or comparable foreign authorities could also request that we enter into a consent decree or a corporate integrity agreement or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our drug candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition and results of operations. The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including commercial biopharmaceutical enterprises, academic institutions, government agencies and private and public research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies and therapies that are more effective, better tolerated or less costly than any which we are developing, or that would render our drug candidates obsolete and noncompetitive. Even if we obtain regulatory approval for any of our drug candidates, our competitors may succeed in obtaining regulatory approvals for their products earlier than we do. We will also face competition from these third parties in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in- licensing technologies and products complementary to our programs or advantageous to our business. The key competitive factors affecting the success of each of our drug candidates, if approved, are likely to be its efficacy, safety, tolerability, frequency and route of administration, convenience and price, the level of branded and generic competition and the availability of coverage and reimbursement from government and other third- party payors. While no therapies are currently approved for..... a. Zydus Cadila). VK2735, if approved, will compete against therapies that are already approved and marketed for obesity, including Semaglutide (Wegovy ®) and liraglutide (Saxenda ®) from Novo Nordisk A / S, and tirzepatide (Zepbound ™) from Eli Lilly and Company. We are also aware of several programs targeting obesity that are in the late development stage that will compete against VK2735, if approved, including CagriSema from Novo Nordisk A / S, orforglipron and retatrutide from Eli Lilly and Company, and survodutide (BI 456906) from Boehringer Ingelheim International GmbH. In addition, we are aware of active programs at Altimmune, Inc., Amgen Inc., **Ascletis Pharma Inc.,** AstraZeneca **, BioAge Labs, Corxel** , D & D Pharmatech, Inc., ERX Pharmaceuticals Inc., F. Hoffmann- La Roche Ltd, **Gubra,** Hanmi Pharmaceutical Co., Ltd., **Kailera Therapeutics,** Kallyope Inc., **Metsera, NeuroBo, NodThera,** Pfizer **Inc., QL Pharma Co., Regeneron Pharmaceuticals** Inc., Rivus Pharmaceuticals Inc., **Sciwind Biosciences Co., Ltd., Scholar Rock,** Structure Therapeutics Inc., Terns Pharmaceuticals, **Inc., Veru** Inc., and Zealand Pharma A / S **While no** ~~),another agonist of the thyroid hormone receptor beta,or TRß,from Madrigal Pharmaceuticals,Inc.,is the only therapy~~ **therapies are** currently approved ~~in the U.S.~~ for the treatment of **non- alcoholic steatohepatitis** ~~NASH / MASH.In addition~~ ,we are aware of numerous development-stage programs targeting this disease,including **resmetirom from Madrigal Pharmaceuticals,Inc.,** arachidyl amido cholanoic acid from Galmed Pharmaceuticals Ltd.,belapectin from Galectin Therapeutics Inc.,lanifibranor from Inventiva S.A.,semaglutide from Novo Nordisk A / S,firsocostat (GS- 0976) and cilofexor (GS- 9674) from Gilead Sciences,Inc.,tirzepatide from Eli Lilly and Company,ervogastat (PF- 06865571) and clesacostat (PF- 05221304) from Pfizer Inc.,efruxifermin (AKR- 001) from Akero Therapeutics,Inc.,pegozafermin (BIO89- 100) from 89bio,Inc.,denifanstat (TVB-2640) from Sagimet Biosciences Inc.,efocipegtrutide (HM15211) from Hanmi Pharmaceutical Co.,Ltd.,survodutide (BI 456906) from Boehringer Ingelheim International GmbH,ION224 ~~and ION839~~ from Ionis Pharmaceuticals,Inc.,rencofilstat (CRV431) from Hepion Pharmaceuticals,Inc.,HTD1801 from HighTide Therapeutics Inc.,GSK4532990 (ARO- HSD) from GlaxoSmithKline plc.,ALN- HSD from Alnylam Pharmaceuticals,Inc./ Regeneron Pharmaceuticals Inc.,efinopegdutide (MK-6024) from Merck & Co.,Inc.,and pemvidutide (ALT- 801) from Altimmune,Inc.In addition,we are aware of active programs at Aligos Therapeutics,Inc.,Arrowhead Pharmaceuticals,Inc.,Ascletis Biopharmaceutical,AstraZeneca PLC,Boston Pharmaceuticals Inc.,Can- Fite BioPharma Ltd.,ChemomAb Ltd.,CohBar,Inc.,Corcept Therapeutics Inc.,CytoDyn Inc.,D & D Pharmatech,Inc.,Durect Corporation,Enyo Pharma SA,Inc.,Future Medicine Co.,Ltd.,Galecto,Inc.,Gelesis Holdings Inc.,Hepagene Therapeutics,Inc.,Kowa Company,Ltd.,MediciNova Inc., **NGM Biopharmaceuticals,Inc.,NorthSea Therapeutics BV,Pliant Therapeutics,Inc.,Poxel SA,** Seal Rock Therapeutics,Inc.,Theratechnologies Inc.,Yuhan Corporation,and Cadila Healthcare Limited (a.k.a. **Zydus Cadila).** . In the U. S., there are currently no marketed therapies for the treatment of ~~X- linked adrenoleukodystrophy, or~~ X- ALD. Hematopoietic stem cell therapy has been used to treat the most severe form of X- ALD, cerebral adrenoleukodystrophy, or CALD. More recently, gene therapy has been shown to be effective in CALD, and elivaldogene autotemcel from bluebird bio, Inc., has received accelerated approval by the FDA (to slow the progression of neurologic dysfunction in boys 4- 17 years of age with early, active CALD), and approval by the European Commission (for patients less than 18 years of age with early CALD without a matched sibling donor). However, both

treatments are invasive, requiring surgical intervention, and these do not appear to have an effect on the most pervasive form of X- ALD, adrenomyeloneuropathy, or AMN. There are several experimental therapies that are in various stages of clinical development for X- ALD by companies, including Minoryx Therapeutics S. L., Neuraxpharm Group, Poxel SA, and **Spur Therapeutics, Inc. (formerly** SwanBio Therapeutics ~~,~~ Inc. **)** , which may be competitive with VK0214, if approved. In the U. S., there are currently no marketed therapies for the maintenance or improvement of lean body mass, bone mineral density or physical function in patients recovering from non- elective hip fracture surgery. However, VK5211, if approved, will face competition from experimental therapies that are in various stages of clinical development for conditions characterized by muscle wasting by companies including Biophytis SA, **and** Helsinn Group ~~, and Pluri Inc. (formerly Pluristem Therapeutics Inc.)~~ . In addition, nutritional and growth hormone- based therapies are sometimes used in patients experiencing muscle wasting. We, or any future collaborators, may not be able to obtain orphan drug designation or orphan drug exclusivity for our product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the United States. While we received orphan drug designation from the FDA for VK0214 for the treatment X- ALD in December 2016, we, or any future collaborators, may not be granted orphan drug designations for our product candidates in the U. S. or in other jurisdictions. Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain orphan drug exclusivity for that product candidate. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. **Additionally, in Catalyst Pharms., Inc. v. Becerra, 14 F. 4th 1299 (11th Cir. 2021), the court disagreed with the FDA' s longstanding position that the orphan drug exclusivity only applies to the approved use or indication within the relevant orphan drug designation. This decision created uncertainty in the application of the orphan drug exclusivity. In January 2023, the FDA published a notice in the Federal Register to clarify that while the FDA complies with the court' s order in Catalyst, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the Catalyst order – that is, the agency will continue tying the scope of orphan- drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, FDA decisions, and administrative actions will impact the scope of the orphan drug exclusivity.** Even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because FDA has taken the position that, under certain circumstances, another drug with the same active moiety can be approved for the same condition. Specifically, the FDA' s regulations provide that it can approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our drug candidates. The process of manufacturing our drug candidates is complex, highly regulated and subject to several risks. For example, the process of manufacturing our drug candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our drug candidates could result in reduced production yields, product defects and other supply disruptions. If microbial, viral, or other contaminations are discovered in our drug candidates or in the manufacturing facilities in which our drug candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, the manufacturing facilities in which our drug candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, epidemics, pandemics, power failures and numerous other factors. In addition, any adverse developments affecting manufacturing operations of our drug candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls, or other interruptions in the supply of our drug candidates. We also may need to take inventory write- offs and incur other charges and expenses for drug candidates that fail to meet specifications, undertake costly remediation efforts, or seek costlier manufacturing alternatives. We rely completely on third parties to manufacture our preclinical and clinical drug supplies, and our business, financial condition and results of operations could be harmed if those third parties fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices. We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies for use in our clinical trials, and we lack the **current** resources and the capability to manufacture any of our drug candidates on a clinical or commercial scale. We rely on our manufacturers to purchase from third- party suppliers the materials necessary to produce our drug candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs, and there may be a need to identify alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our drug candidates for our clinical trials, and, if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a drug candidate to complete such clinical trial, any significant delay or discontinuity in the supply of a drug candidate, or the raw material components thereof, for an ongoing

clinical trial due to the need to replace a third- party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our drug candidates, which could harm our business, financial condition and results of operations. We and our contract manufacturers are subject to significant regulation with respect to manufacturing our drug candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements. All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our drug candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late- stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our drug candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA or marketing authorization application, or MAA, on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA, EMA or comparable foreign authorities through their facilities inspection program. Some of our contract manufacturers may not have produced a commercially approved pharmaceutical product and therefore may not have obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third- party contractors must pass a pre- approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our drug candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our drug candidates or any of our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third- party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business, financial condition and results of operations. If we or any of our third- party manufacturers fail to maintain regulatory compliance, the FDA, EMA or comparable foreign authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a drug candidate, withdrawal of an approval, or suspension of production. As a result, our business, financial condition and results of operations may be materially and adversely affected. Additionally, if supply from one manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA supplement or MAA variation, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our drug candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed, or we could lose potential revenue. Any collaboration arrangement that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and potential future drug candidates. We may seek collaboration arrangements with biopharmaceutical companies for the development or commercialization of our current and potential future drug candidates. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time- consuming to negotiate, execute and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements, and the terms of the arrangements may not be favorable to us. If, and when, we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement can lead to delays in developing or commercializing the applicable drug candidate and can be difficult to resolve in a mutually beneficial manner. In some cases, collaborations with biopharmaceutical companies and other third parties are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect our business, financial condition and results of operations. If we are unable to develop our own commercial organization or enter into agreements with third parties to sell and market our drug candidates, we may be unable to generate significant revenues. We do not have a sales and marketing organization, and we have no experience as a company in the sales, marketing and distribution of pharmaceutical products. If any of our drug candidates are approved for commercialization, we may be required to develop our sales, marketing and distribution capabilities, or make arrangements with a third party to perform sales and marketing services. Developing a sales force for any resulting product or any product resulting from any of our other drug candidates is expensive and time- consuming and could delay any product launch. We may be unable to establish and manage an effective sales force in a timely or cost- effective manner, if at all, and any sales force we do establish may not be capable of generating sufficient demand for our drug candidates. To the extent that

we enter into arrangements with collaborators or other third parties to perform sales and marketing services, our product revenues are likely to be lower than if we marketed and sold our drug candidates independently. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenues and may not become profitable. The commercial success of our drug candidates depends upon their market acceptance among physicians, patients, healthcare payors and the medical community. Even if our drug candidates obtain regulatory approval, our products, if any, may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any of our approved drug candidates will depend on a number of factors, including: • the effectiveness of our approved drug candidates as compared to currently available products; • patient willingness to adopt our approved drug candidates in place of current therapies; • our ability to provide acceptable evidence of safety and efficacy; • relative convenience and ease of administration; • the prevalence and severity of any adverse side effects; • restrictions on use in combination with other products; • availability of alternative treatments; • pricing and cost- effectiveness assuming either competitive or potential premium pricing requirements, based on the profile of our drug candidates and target markets; • effectiveness of our or our partners' sales and marketing strategy; • our ability to obtain sufficient third- party coverage or reimbursement; and • potential product liability claims. In addition, the potential market opportunity for our drug candidates is difficult to precisely estimate. Our estimates of the potential market opportunity for our drug candidates include several key assumptions based on our industry knowledge, industry publications, third- party research reports and other surveys. Independent sources have not verified all of our assumptions. If any of these assumptions proves to be inaccurate, then the actual market for our drug candidates could be smaller than our estimates of our potential market opportunity. If the actual market for our drug candidates is smaller than we expect, our product revenue may be limited, it may be harder than expected to raise funds and it may be more difficult for us to achieve or maintain profitability. If we fail to achieve market acceptance of our drug candidates in the U. S. and abroad, our revenue will be limited and it will be more difficult to achieve profitability. If we fail to obtain and sustain an adequate level of reimbursement for our potential products by third- party payors, potential future sales would be materially adversely affected. There will be no viable commercial market for our drug candidates, if approved, without reimbursement from third- party payors. Reimbursement policies may be affected by future healthcare reform measures. We cannot be certain that reimbursement will be available for our current drug candidates or any other drug candidate we may develop. Additionally, even if there is a viable commercial market, if the level of reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected. Third- party payors, such as government or private healthcare insurers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. There is a current trend in the U. S. healthcare industry toward cost containment. Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third- party payors limit coverage of or reimbursement for newly approved healthcare products. In particular, third- party payors may limit the covered indications. Cost- control initiatives could decrease the price we might establish for products, which could result in product revenues being lower than anticipated. We believe our drugs will be priced significantly higher than existing generic drugs and consistent with current branded drugs. If we are unable to show a significant benefit relative to existing generic drugs, Medicare, Medicaid and private payors may not be willing to provide reimbursement for our drugs, which would significantly reduce the likelihood of our products gaining market acceptance. We expect that private insurers will consider the efficacy, cost- effectiveness, safety and tolerability of our potential products in determining whether to approve reimbursement for such products and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business, financial condition and results of operations would be materially adversely affected if we do not receive approval for reimbursement of our potential products from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part D, which provides a pharmacy benefit to Medicare patients as discussed below, does not require participating prescription drug plans to cover all drugs within a class of products. Our business, financial condition and results of operations could be materially adversely affected if Part D prescription drug plans were to limit access to, or deny or limit reimbursement of, our drug candidates or other potential products. Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country- by- country basis. In many countries, the product cannot be commercially launched until reimbursement is approved. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. The negotiation process in some countries can exceed 12 months. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our products to other available therapies. If the prices for our potential products are reduced or if governmental and other third- party payors do not provide adequate coverage and reimbursement of our drugs, our future revenue, cash flows and prospects for profitability will suffer. Current and future legislation may increase the difficulty and cost of commercializing our drug candidates and may affect the prices we may obtain if our drug candidates are approved for commercialization. In the U. S. and some foreign jurisdictions, there have been a number of adopted and proposed legislative and regulatory changes regarding the healthcare system that could prevent or delay regulatory approval of our drug candidates, restrict or regulate post- marketing activities and affect our ability to profitably sell any of our drug candidates for which we obtain regulatory approval. In the U. S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit the coverage and reimbursement rate that we receive for

any of our approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the PPACA, was enacted. The PPACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The PPACA increased manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate amount for both branded and generic drugs and revised the definition of " average manufacturer price, " or AMP, which may also increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also expanded Medicaid drug rebates and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the rebates due on those drugs. The Centers for Medicare & Medicaid Services, or CMS, which administers the Medicaid Drug Rebate Program, also has proposed to expand Medicaid rebates to the utilization that occurs in the territories of the U. S., such as Puerto Rico and the Virgin Islands. Further, beginning in 2011, the PPACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a discount, equal to 70 % off, effective as of 2019, the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the " donut hole. " Legislative and regulatory proposals have been introduced at both the state and federal level to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. We also expect that additional U. S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U. S. federal government will pay for healthcare products and services, which could result in reduced demand for our drug candidates, if approved for commercialization. In Europe, the United Kingdom withdrew from the European Union on January 31, 2020, and entered into a transition period that expired on December 31, 2020. A significant portion of the previous regulatory framework in the United Kingdom was derived from the regulations of the European Union. In 2021, the United Kingdom' s Medicines and Healthcare products Regulatory Agency, or MHRA, and the European Medicines Agency, or EMA, released guidance explaining the new regulatory framework. We cannot predict the consequences or impact that the new regulatory framework will have on our future operations, if any, in these jurisdictions. In addition, on August 16, 2022, ~~President Biden~~ **the Inflation Reduction Act of 2022 was** signed into law ~~the Inflation Reduction Act of 2022,~~ which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, which **took** ~~shall take~~ effect in 2023. Under the Inflation Reduction Act, Congress authorized Medicare beginning in 2026 to negotiate lower prices for certain costly single- source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year and it only applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. Further, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference. The new law also caps Medicare out- of- pocket drug costs at an estimated ~~$ 4, 000 a year in 2024 and, thereafter beginning in 2025, at~~ $ 2, 000 a year. Changes in government funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, properly administer drug innovation, or prevent our product candidates from being developed or commercialized, which could negatively impact our business, financial condition and results of operations. The ability of the FDA to review and approve new products can be affected by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, and statutory, regulatory and policy changes. In addition, there may be delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. In December 2016, the 21st Century Cures Act was signed into law. This legislation is designed to advance medical innovation and empower the FDA with the authority to directly hire positions related to drug and device development and review. However, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may result in a reduced ability by the FDA to perform its roles, including the related impact to academic institutions and research laboratories whose funding is fully or partially dependent on both the level and timing of funding from government sources. Disruptions at the FDA and other agencies may also slow the time necessary for our product candidates to be reviewed or approved by necessary government agencies, which could adversely affect our business, financial condition and results of operations. We are subject to " fraud and abuse " and similar laws and regulations, and a failure to comply with such regulations or prevail in any litigation related to noncompliance could harm our business, financial condition and results of operations. In the U. S., we are subject to various federal and state healthcare " fraud and abuse " laws, including anti- kickback laws, false claims laws and other laws intended, among other things, to reduce fraud and abuse in federal and state healthcare programs. The federal Anti- Kickback Statute makes it illegal for any person, including a prescription drug manufacturer, or a party acting

on its behalf, to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug, or other good or service for which payment in whole or in part may be made under a federal healthcare program, such as Medicare or Medicaid. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti- Kickback Statute. The federal False Claims Act prohibits anyone from, among other things, knowingly presenting or causing to be presented for payment to the government, including the federal healthcare programs, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services to obtain money or property of any healthcare benefit program. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including penalties, fines or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U. S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states. Many states have adopted laws similar to the federal Anti- Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers or the Pharmaceutical Research and Manufacturers of America' s Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If we are found in violation of one of these laws, we could be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from governmental funded federal or state healthcare programs and the curtailment or restructuring of our operations. If this occurs, our business, financial condition and results of operations may be materially adversely affected. If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and any of our drug candidates that are ultimately approved for commercialization could be subject to restrictions or withdrawal from the market. Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to generate revenues from any of our drug candidates that are ultimately approved for commercialization. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business, financial condition and results of operations will be adversely affected. Additionally, if we are unable to generate revenues from product sales, our potential for achieving profitability will be diminished and our need to raise capital to fund our operations will increase. Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations. The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, the EU, including personal health data, is subject to the EU General Data Protection Regulation, or the GDPR, which took effect across all member states of the European Economic Area, or the EEA, in May 2018. The GDPR is wide- ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third- party processors. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, which includes the United States and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal ~~information~~ **data** and / or impose substantial fines for violations of the GDPR, which can be up to 4 % of global revenues or € 20 million, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU member states may make their own additional laws and regulations limiting the processing of personal data, including genetic, biometric or health data. **The European Data Protection Board continues to release guidelines for industries and impose fines related to the GDPR, some of which have been very significant. To improve coordination among EU supervisory authorities, the European Commission has proposed a new regulation that would help to streamline enforcement of the GDPR in cross- border cases. Meanwhile, there continues to be persistent uncertainty relating to the transfer of personal**

data from Europe to the U. S., or other non- adequate countries, following the Schrems II decision. On July 10, 2023, the European Commission adopted its adequacy decision on the EU- U. S. Data Privacy Framework, or DPF. The decision, which took effect on the day of its adoption, concludes that the United States ensures an adequate level of protection for personal data transferred from the EEA to companies certified to DPF. However, it remains too soon to tell how the future of DPF will evolve and what impact it will have on our international activities. At least one challenge to the DPF is pending before the Court of Justice of the European Union. Further, Brexit has led and could also lead to legislative and regulatory changes that may increase our compliance costs. As of January 1, 2021 and the expiry of transitional arrangements agreed to between the UK and the EU, data processing in the UK is governed by a UK version of the GDPR (combining the GDPR and the Data Protection Act 2018), exposing us to two parallel regimes, each of which authorizes similar fines and other potentially divergent enforcement actions for certain violations. On June 28, 2021, the European Commission adopted an Adequacy Decision for the UK, allowing for the relatively free exchange of personal data between the EU and the UK (as the UK correspondingly allows transfers back to the EU). However, the European Commission may suspend the Adequacy Decision if it considers that the UK no longer provides for an adequate level of data protection. A bill to amend the existing UK framework has been reintroduced (in a different form) by the new UK Government and was announced as a bill which will be introduced into Parliament at the King' s Speech on July 17, 2024. At this time, there is no specific clarity on the provisions of the bill, or the extent to which it will amend the UK framework, beyond general descriptions on its intended purpose. Similar actions are either in place or under way in the United States. There are a broad variety of data protection **and breach notification** laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. ~~The~~ **Each of these laws is subject to varying interpretations and the legislative landscape is constantly evolving and the** Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. ~~New~~ **At the federal level, for example, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which establishes privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. Requirements for compliance under HIPAA are also subject to change, as the U. S. Department of Health and Human Services Office of Civil Rights issued a proposed rule that would amend certain security compliance requirements for covered entities and business associates. Additionally, new** laws also are being considered at both the state and federal levels and several states have passed comprehensive privacy laws. For example, the California Consumer Privacy Act, or the CCPA, which went into effect on January 1, 2020, is creating similar risks and obligations as those created by the GDPR, though the CCPA does exempt certain clinical trial data. The California Privacy Rights Act, or the CPRA, which went into effect on January 1, 2023, amended and expanded the CCPA, and also created a new state agency that is vested with authority to implement and enforce the CCPA and the CRPA. The CCPA and the CRPA may increase our compliance costs and potential liability, and we cannot yet predict the impact of the CCPA or the CRPA on our business. Similar laws passed in Virginia, Colorado, Connecticut, and Utah took effect in 2023 **while laws in Oregon, Montana and Texas went into effect in 2024** . Additionally, Delaware, **Florida,** Indiana, Iowa, ~~Montana~~ **Kentucky** , ~~Oregon~~ **Maryland** , **Minnesota, Nebraska, New Hampshire, New Jersey, Rhode Island, and** Tennessee ~~and Texas~~ have adopted privacy laws, which **took or will** take effect from ~~July~~ **January** 1, ~~2024~~ **2025** through 2026. ~~Further~~ **Some state laws also minimize what data can be collected from consumers and how businesses may use and disclose it. These state privacy laws also require businesses to make disclosures to consumers about data collection , use and sharing practices. In addition, some of these laws (including the CPRA), along with other standalone health privacy laws, subject health- related information to additional safeguards and disclosures and some specifically regulate consumer health data, such as the** Washington ~~' s~~ My Health My Data Act, ~~taking~~ **which became** ~~effect~~ **effective** ~~July 1,~~ **in 2023 and** 2024, **Nevada' s** ~~imposes similar requirements specific to consumer~~ **Consumer Health Data Privacy Law, which became effective in 2024, and Connecticut' s amendments to its privacy law to address** health data **, which became effective in 2023** . Additionally, a broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal ~~information~~ **data** could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third- party collaborators, service providers, CROs, contractors or consultants that process or transfer personal data collected in the EU. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal ~~information~~ **data** from our clinical trials **, and access to certain data such as the European Health Data Space Regulation** , could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations. Similarly, failure to comply with federal and state laws regarding privacy and security of

personal ~~information~~ **data** could expose us to fines and penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business. We are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations. If we fail to comply with these laws, we could be subject to civil or criminal liabilities, other remedial measures and legal expenses, be precluded from developing, manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition. Our operations are subject to anti- corruption laws, including the U. S. Foreign Corrupt Practices Act, or the FCPA, the U. K. Bribery Act 2010, or the Bribery Act, and other anti- corruption laws that apply in countries where we do business and may do business in the future. The FCPA, the Bribery Act and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, the Bribery Act or local anti- corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, the United Kingdom and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as Trade Control Laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non- U. S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, we will be required to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti- corruption laws, including the FCPA, the Bribery Act or other legal requirements, including Trade Control Laws. If we are not in compliance with the FCPA, the Bribery Act and other anti- corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. Any investigation of any potential violations of the FCPA, the Bribery Act, other anti- corruption laws or Trade Control Laws by United States, United Kingdom or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition. Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any. In some countries, particularly member states of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce prices. In some countries, we, or our future collaborators, may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third- party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed. If we fail to retain current members of our senior management and scientific personnel, or to attract and keep additional key personnel, we may be unable to successfully develop or commercialize our drug candidates. Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. As of December 31, ~~2023~~ **2024** , we had ~~twenty~~ **thirty** - ~~seven~~ **six** full- time employees **, one part- time employee** and a small number of consultants, which may make us more reliant on our individual employees than companies with a greater number of employees. The loss of any of our key personnel could delay or prevent the development of our drug candidates. These personnel are " at-will " employees and may terminate their employment with us at any time; however, **each of** our current **chief** executive **officer and current chief financial** officer has agreed to provide us with at least 60 days' advance notice of **his respective** resignation pursuant to his employment agreement with us. The replacement of key personnel likely would involve significant time and costs, and may significantly delay or prevent the achievement of our business objectives. We do not maintain " key person " insurance on any of our employees. From time to time, our management seeks the advice and guidance of certain scientific advisors and consultants regarding clinical and regulatory development programs and other customary matters. These scientific

advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our scientific advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. Competition for qualified personnel is intense, especially in the greater San Diego, California area where we have a substantial presence and need for highly skilled personnel. We may not be successful in attracting qualified personnel to fulfill our current or future needs. Competitors and others have in the past attempted, and are likely in the future to attempt, to recruit our employees. While our employees are required to sign standard agreements concerning confidentiality and ownership of inventions, we generally do not have employment contracts or non- competition agreements with any of our personnel. In addition, we may experience employee turnover as a result of the ongoing " great resignation " occurring throughout the U. S. economy, which has impacted job market dynamics. New hires require training and take time before they achieve full productivity. New employees may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals. The loss of the services of any of our key personnel, the inability to attract or retain highly qualified personnel in the future or delays in hiring such personnel, particularly senior management and other technical personnel, could materially and adversely affect our business, financial condition and results of operations. We will need to increase the size of our organization and may not successfully manage our growth. We are a clinical- stage biopharmaceutical company with a small number of employees, and our management systems currently in place are not likely to be adequate to support our future growth plans. Our ability to grow and to manage our growth effectively will require us to hire, train, retain, manage and motivate additional employees and to implement and improve our operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. Hiring a significant number of additional employees, particularly those at the management level, would increase our expenses significantly. Moreover, if we fail to expand and enhance our operational, financial and management systems in conjunction with our potential future growth, it could have a material adverse effect on our business, financial condition and results of operations. We are exposed to product liability, non- clinical and clinical liability risks which could place a substantial financial burden upon us, should lawsuits be filed against us. Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. In addition, the use in our clinical trials of pharmaceutical products and the subsequent sale of these products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations. We currently maintain product liability insurance; however, there can be no assurance that we will be able to continue to maintain such insurance, and we may be unable to obtain replacement product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business. Our research and development activities involve the use of hazardous materials, which subject us to regulation, related costs and delays and potential liabilities. Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds, and we will need to develop additional safety procedures for the handling and disposing of hazardous materials. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood- borne pathogens and the handling of biohazardous materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate any of these laws or regulations. We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively. Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract, including our CROs and other business partners, are vulnerable to damage from cyber- attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations or the operations of our CROs and other business partners, and could result in a material disruption of our drug development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of drug development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. **We have experienced cybersecurity incidents in the past and expect that we will experience cybersecurity incidents in the future. If we were to experience a significant cybersecurity breach of our information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counter- parties and data subjects could be material.** To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our drug candidates could be delayed **. Artificial intelligence presents risks and challenges that can impact our business, including by posing security risks to our confidential information, proprietary information and personal data. Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with**

respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third- party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and have a material adverse effect on our business, financial condition and results of operations . Our employees and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee or consultant fraud or other misconduct. Misconduct by our employees or consultants could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Employee and consultant misconduct also could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter 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 be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us. Business disruptions such as natural disasters could seriously harm our future revenues and financial condition and increase our costs and expenses. Our corporate headquarters are located in greater San Diego, California, a region known for seismic activity. In addition, one of our third- party manufacturers is located in the southeastern part of the United States, an area subject to hurricanes and related natural disasters. Our suppliers may also experience a disruption in their business as a result of natural or man- made disasters. A significant natural or man- made disaster, such as an earthquake, prolonged or repeated power outage, hurricane, flood, fire, drought or other extreme weather events and changing weather patterns, which are increasing in frequency due to the impacts of climate change, could severely damage or destroy our headquarters or facilities or the facilities of our manufacturers or suppliers, which could have a material and adverse effect on our business, financial condition and results of operations. In addition, terrorist acts or acts of war targeted at the U. S., and specifically the greater San Diego, California region, as well as the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia and the Israel- Hamas war, could cause damage or disruption to us, our employees, facilities, partners and suppliers, which could have a material adverse effect on our business, financial condition and results of operations. We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management. From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out- licensing or in- licensing of products, drug candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin- offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non- recurring or other charges, may increase our near- and long- term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our business, financial condition and results of operations. For example, these transactions may entail numerous operational and financial risks, including: • exposure to unknown liabilities; • disruption of our business and diversion of our management' s time and attention in order to develop acquired products, drug candidates or technologies; • incurrence of substantial debt or dilutive issuances of equity securities to pay for any of these transactions; • higher- than- expected transaction and integration costs; • write- downs of assets or goodwill or impairment charges; • increased amortization expenses; • difficulty and cost in combining the operations and personnel of any acquired businesses or product lines with our operations and personnel; • impairment of relationships with key suppliers or customers of any acquired businesses or product lines due to changes in management and ownership; and • inability to retain key employees of any acquired businesses. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks, and could have a material adverse effect on our business, financial condition and results of operations. Our employment agreements with our officers and certain other employees may require us to pay severance benefits to any of those persons who are terminated in connection with a change in control of our company, which could harm our financial condition or results. Our officers and certain employees are parties to employment agreements that contain change in control and severance provisions in the event of a termination of employment in connection with a change in control of our company providing for cash payments for severance and other benefits and acceleration of vesting of stock options and shares of restricted stock. The accelerated vesting of options and shares of restricted stock could result in dilution to our existing stockholders and lower the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us. ~~Investors'~~ **Our ability to effectively monitor and respond to the rapid and evolving developments and** expectations ~~of our performance~~ relating to **sustainability, including** environmental, social and governance ~~factors~~ **matters,** may impose ~~additional~~ **unexpected** costs ~~and expose us to new risks~~ **or results in reputational or other harm that could have a material**

adverse effect on our business . There is an increasing focus from certain investors, employees, regulators **, listing exchanges** and other stakeholders concerning corporate responsibility **and sustainability matters** , ~~specifically related to~~ **including with regarding** environmental, social and governance ~~, or ESG,~~ factors. Some investors and investor ~~advocacy~~ groups may use these factors ~~—~~ **either positively or negatively —** to guide **their** investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies **or practices** relating to corporate responsibility ~~are inadequate~~ **and sustainability do not align with their expectations** . **Currently, a number of** ~~Third~~ **third** - party providers of corporate responsibility **and sustainability** ratings ~~and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently~~ measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers **,** and **some major institutional investors have publicly emphasized the importance of these measures to their investment decisions. Topics taken into account in such assessments include, among others, companies' efforts and impacts on climate change, human rights, business ethics and compliance, diversity, equity and inclusion and the role of companies' board of directors in overseeing various sustainability- related issues. In light of investors' increased focus on these matters,** if we are **, for example,** perceived as lagging **in taking steps** with respect to ~~ESG~~ **these** initiatives, certain investors may **seek to** engage with us ~~to~~ **on** ~~improve~~ **improving** ~~ESG~~ **our corporate responsibility and sustainability** disclosures or performance ~~and~~ **. They** may also make voting decisions ~~,~~ or take other actions ~~,~~ to hold us and our board of directors accountable. In addition **, there are rapidly evolving developments and changing expectations relating to sustainability matters. As a result** , the criteria by which our corporate responsibility **and sustainability** practices are assessed may change, which could ~~result in greater expectations of us and~~ cause us to undertake costly initiatives **or actions** to satisfy ~~such~~ new ~~criteria~~ **demands** . If we elect not to or are unable to ~~satisfy~~ **adequately recognize and respond to** such ~~new criteria~~ **developments and changing governmental** , **societal,** ~~investors~~ **investor and / or consumer expectations relating to sustainability matters, we** may ~~conclude~~ **miss corporate opportunities, become subject to additional scrutiny or incur unexpected costs. We may face risk of litigation or reputational damage in the event** that our **sustainability** policies ~~with respect to corporate responsibility are inadequate~~ **or practices do not meet the standards set by various constituencies** . We may **also** face reputational damage ~~in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or~~ if we are unable to achieve an acceptable ~~ESG or sustainability~~ rating from third- party rating services. A low ~~ESG or sustainability~~ rating by a third- party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our ~~competition~~ **competitors** instead. Ongoing focus on corporate responsibility **and sustainability** matters by investors and other ~~parties~~ **stakeholders** as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, ~~share price,~~ financial condition, or results of operations, including the sustainability of our business over time **, and could cause the market value of our common stock to decline. Further, our emphasis on sustainability issues may not maximize short- term financial results and may yield financial results that conflict with the market' s expectations. We may in the future make business decisions consistent with our sustainability goals that we believe, based on considered analysis, will create value and improve our financial performance over the long- term. These decisions, however, may not be consistent with the short- term expectations of our stockholders and may not produce the long- term benefits that we expect, in which case our business, financial condition and results of operations could be harmed** . In addition, **on March 6, 2024,** the SEC **finalized new** ~~has announced proposed~~ rules **for public companies** that **will require extensive climate- related disclosures and significant analysis of the impact of climate- related issues on our business strategy, results of operations, and financial condition, or the SEC Climate Disclosure Rules, and extensive attestation requirements. The new rules require disclosure of** , among other ~~matters~~ **things and to the extent material** , **our** ~~will establish a framework for reporting of~~ climate- related risks **and opportunities, greenhouse gas emissions inventory, climate- related targets and goals, and financial impacts of physical and transition risks** . ~~To~~ **Subsequently, in April 2024,** the ~~extent~~ **SEC issued an order staying implementation of** the ~~proposed~~ **SEC Climate Disclosure** ~~rules~~ **Rules** ~~impose additional reporting obligations~~ **pending the resolution of certain challenges. Nonetheless** , ~~we could face~~ **our legal, accounting, and other compliance expenses may** ~~increased~~ **increase** ~~costs~~ **significantly, and compliance efforts may divert management time and attention as we prepare for the potential implementation of the SEC Climate Disclosure Rules, and such expenses, efforts and diversions of management time and attention may be even greater if the SEC Climate Disclosure Rules ultimately go into effect. We may also be exposed to legal or regulatory action or claims as a result of these new regulations** . Separately, the SEC has also announced that it is scrutinizing existing climate- change related disclosures in public filings, increasing the potential for enforcement if the SEC were to allege our existing climate disclosures are misleading or deficient. **All of these risks could have a material adverse effect on our business, financial position, and / or stock price.** The impact of the Russian invasion of Ukraine and the Israel- Hamas war on the global economy, energy supplies and raw materials is uncertain, but may prove to negatively impact our business and operations. The short and long- term implications of Russia' s invasion of Ukraine and the Israel- Hamas war are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine, the subsequent institution of sanctions against Russia by the United States and several European and Asian countries, and the Israel- Hamas war may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and other third parties with which we conduct business. For example, a prolonged conflict in Ukraine or Israel may result in increased inflation, escalating energy prices and constrained availability, and thus increasing costs, of raw materials. We will continue to monitor this fluid situation and develop contingency plans as necessary to address any disruptions to our business operations as they develop. To the extent the wars in Ukraine or Israel may adversely affect our business as discussed above, it may also have the effect of heightening

many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation; disruptions to our global technology infrastructure, including through cyberattack, ransom attack, or cyber- intrusion; adverse changes in international trade policies and relations; disruptions in global supply chains; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect our business and financial condition. Our business, financial condition and results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, service providers, manufacturers or other partners and there is a risk that one or more would not survive or be able to meet their commitments to us under such circumstances. ~~As widely reported, global credit and financial markets have experienced volatility and disruptions in the past several years and especially in 2020, 2021 and 2022 due to the impacts of the COVID- 19 pandemic, and, more recently, the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Moreover, the global impacts of the Israel- Hamas war are still unknown.~~ There can be no assurances that ~~further~~ deterioration in **the** credit and financial markets and confidence in economic conditions will not occur. For example, U. S. debt ceiling and budget deficit concerns have increased the possibility of additional credit- rating downgrades and economic slowdowns, or a recession in the United States. Although U. S. lawmakers passed legislation to raise the federal debt ceiling on multiple occasions, including a suspension of the federal debt ceiling in June 2023, ratings agencies have lowered or threatened to lower the long- term sovereign credit rating on the United States. The impact of this or any further downgrades to the U. S. government' s sovereign credit rating or its perceived creditworthiness could adversely affect the U. S. and global financial markets and economic conditions. Absent further quantitative easing by the Federal Reserve, these developments could cause interest rates and borrowing costs to rise, which may negatively impact our results of operations or financial condition. Moreover, disagreement over the federal budget has caused the U. S. federal government to shut down for periods of time. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Risks Relating to Our Intellectual Property We currently have intellectual property rights to develop our drug candidates through a license from Ligand. As of December 31, ~~2023~~ **2024** , we owned or co- owned ~~92~~ **144** patent applications and ~~23~~ **35** patents. Because our programs require the use of proprietary rights held by Ligand, the growth of our business will likely depend in part on our ability to maintain and exploit these proprietary rights. In addition, we may need to acquire or in- license additional intellectual property in the future. We may be unable to acquire or in- license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our drug candidates. We face competition with regard to acquiring and in- licensing third- party intellectual property rights, including from a number of more established companies. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license intellectual property rights to us. We also may be unable to acquire or in- license third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment. We may enter into collaboration agreements with U. S. and foreign academic institutions to accelerate development of our current or future preclinical drug candidates. Typically, these agreements include an option for us to negotiate a license to the institution' s intellectual property rights resulting from the collaboration. Even with such an option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to license rights from a collaborating institution, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our desired program. If we are unable to successfully obtain required third- party intellectual property rights or maintain our existing intellectual property rights, including if our patent applications do not result in the issuance of patents, we may need to abandon development of the related program and our business, financial condition and results of operations could be materially and adversely affected. The Master License Agreement is important to our business and we expect to enter into additional license agreements in the future. The Master License Agreement imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or if we file for bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses could materially and adversely affect our business, financial condition and results of operations. Pursuant to the terms of the Master License Agreement, Ligand may terminate the Master License Agreement under certain circumstances, including, but not limited to: (1) in the event of our insolvency or bankruptcy, (2) if we do not pay an undisputed amount owing under the Master License Agreement when due and fail to cure such default within a specified period of time, or (3) if we default on certain of our material obligations and fail to cure the default within a specified period of time. If the Master License Agreement is terminated in its entirety or with respect to a specific licensed program for any reason, among other consequences, all licenses granted to us under the Master License Agreement (or with respect to the specific licensed program) will terminate and we may be requested to assign and transfer to Ligand certain regulatory documentation and regulatory approvals related to the licensed programs (or those related to the specific licensed program), and we may be required to wind down any ongoing clinical trials with respect to the licensed programs (or those related to the specific licensed program). Additionally, Ligand may require us to assign to Ligand the trademarks owned by us relating to the licensed programs (or those related to the specific licensed program), and we would be obligated to grant to Ligand a license under any patent rights and know- how controlled by us to the extent necessary to make, have made, import, use, offer to sell and sell the licensed programs (or those related to the specific licensed program) anywhere in the world at a

royalty rate in the low single digits. In some cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we in- license, then we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we may control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including, but not limited to: • the scope of rights granted under the license agreement and other interpretation- related issues; • the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • the sublicensing of patent and other rights; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and • the priority of invention of patented technology. If disputes over intellectual property and other rights that we have in- licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates. If we fail to comply with any such obligations to our licensor, such licensor may terminate their licenses to us, in which case we would not be able to market products covered by these licenses. The loss of our license with Ligand, and potentially other licenses that we enter into in the future, would have a material adverse effect on our business. We may be required to pay milestones and royalties to Ligand in connection with our use of the licensed technology under the Master License Agreement, which could adversely affect the overall profitability for us of any products that we may seek to commercialize. Under the terms of the Master License Agreement, we may be obligated to pay Ligand up to an aggregate of approximately $ 1. 54 billion in development, regulatory and sales milestones. We will also be required to pay Ligand single- digit royalties on future worldwide net product sales. These royalty payments could adversely affect the overall profitability for us of any products that we may seek to commercialize. We may not be able to protect our proprietary or licensed technology in the marketplace. We depend on our ability to protect our proprietary or licensed technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability, Ligand' s and any future licensor' s or licensee' s ability to obtain and maintain patent protection in the U. S. and other countries with respect to our proprietary or licensed technology and products. We currently in- license most of our intellectual property rights to develop our drug candidates and may in- license additional intellectual property rights in the future. Under the terms of the Master License Agreement, Ligand has the first right to file, prosecute and maintain the patents subject to the Master License Agreement in its name. We cannot be certain that patent enforcement activities by our current or future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. We also cannot be certain that our current or future licensors will allocate sufficient resources or prioritize their or our enforcement of such patents. Even if we are not a party to these legal actions, an adverse outcome could prevent us from continuing to license intellectual property that we may need to operate our business, which would have a material adverse effect on our business, financial condition and results of operations. We believe we will be able to obtain, through prosecution of patent applications covering technology licensed from others, adequate patent protection for our proprietary drug technology, including those related to our in- licensed intellectual property. If we are compelled to spend significant time and money protecting or enforcing our licensed patents and future patents we may own, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business, financial condition and results of operations may be materially and adversely affected. If we are unable to effectively protect the intellectual property that we own or in- license, other companies may be able to offer the same or similar products for sale, which could materially adversely affect our business, financial condition and results of operations. The patents of others from whom we may license technology, and any future patents we may own, may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our products. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection for licensed patents, pending patent applications and potential future patent applications and patents could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or patent applications will be due to be paid to the U. S. Patent and Trademark Office, or the USPTO, and various governmental patent agencies outside of the U. S. in several stages over the lifetime of the applicable patent and / or patent application. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, 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. If this occurs with respect to our in- licensed patents or patent applications we may file in the future, our competitors might be able to use our technologies, which would have a material adverse effect on our business, financial condition and results of operations. The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the U. S. and many jurisdictions outside of the U. S. is not consistent. For example, in many jurisdictions, the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the U. S. and other countries may diminish the value of our licensed or owned intellectual property or create uncertainty. In addition, publication of information related to our current drug candidates and

potential products may prevent us from obtaining or enforcing patents relating to these drug candidates and potential products, including without limitation composition- of- matter patents, which are generally believed to offer the strongest patent protection. Our intellectual property includes licenses covering issued patents and pending patent applications for composition of matter, method of use and method of manufacture. As of December 31, ~~2023~~ **2024**, for each of VK2809 and VK0214, we in-licensed three patents in the U. S. and additional patents in certain foreign jurisdictions, and owned or co- owned and in-licensed ~~two~~ **three** U. S. patents, ~~six~~ **four** U. S. patent applications, and additional patents and patent applications in certain foreign jurisdictions. We also in- licensed one additional U. S. patent and one Japanese patent directed to VK0214, and owned two additional U. S. patents, one PCT application, and several patent applications in the U. S. and certain foreign jurisdictions directed to VK2809 as of December 31, ~~2023~~ **2024**. For VK5211, as of December 31, ~~2023~~ **2024**, we in- licensed ten patents and one patent application in the U. S. and several other patents and patent applications in certain foreign jurisdictions. As of December 31, ~~2023~~ **2024**, for our GLP- 1 program, we own one U. S. patent, ~~four~~ **additional patents in certain foreign jurisdictions, two** PCT applications, and several patent applications in the U. S. and certain foreign jurisdictions. With respect to our other current drug candidates, we have a license covering several issued patents both in the U. S. and in certain foreign jurisdictions. Patents that we currently license and patents that we may own or license in the future do not necessarily ensure the protection of our licensed or owned intellectual property for a number of reasons, including, without limitation, the following: • the patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our drug candidates; • there can be no assurance that the term of a patent can be extended under the provisions of patent term extension afforded by U. S. law or similar provisions in foreign countries, where available; • the issued patents and patents that we may obtain or license in the future may not prevent generic entry into the U. S. market for our drug candidates; • we do not at this time license or own a granted European patent or national phase patents in any European jurisdictions that would prevent generic entry into the European market for one of our primary drug candidates, VK2809; • we, or third parties from who we in-license or may license patents, may be required to disclaim part of the term of one or more patents; • there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim; • there may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim; • there may be other patents issued to others that will affect our freedom to operate; • if the patents are challenged, a court could determine that they are invalid or unenforceable; • there might be a significant change in the law that governs patentability, validity and infringement of our licensed patents or any future patents we may own that adversely affects the scope of our patent rights; • a court could determine that a competitor' s technology or product does not infringe our licensed patents or any future patents we may own; and • the patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing. If we encounter delays in our development or clinical trials, the period of time during which we could market our potential products under patent protection would be reduced. Our competitors may be able to circumvent our licensed patents or future patents we may own by developing similar or alternative technologies or products in a non- infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which our competitors claim that our licensed patents or any future patents we may own are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our licensed patents or any future patents we may own, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our licensed patents or any future patents we may own invalid or unenforceable. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we own or in- license valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In this regard, third parties may challenge our licensed patents or any future patents we may own in the courts or patent offices in the U. S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and potential products. In addition, given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and prevent us from commercializing or increase the costs of commercializing our products. Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our current or potential future drug candidates infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe. Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our drug candidates or potential products infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that our drug candidates or potential products infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional, or continuation- in- part applications, in order to maintain the pendency of a patent family and attempt to cover our drug candidates. Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our business, financial condition and results of operations and divert the attention of managerial and

scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our drug candidates, potential products or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U. S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third- party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our products unless we acquire or obtain a license under the applicable patents or until the patents expire. We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us. 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. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially and adversely affect our business, financial condition and results of operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material and adverse effect on our business, financial condition and results of operations. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. Any claims or lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely affect our business, financial condition and results of operations. We may be required to initiate litigation to enforce or defend our licensed and owned intellectual property. For example, we were previously aware of at least two third- party companies that were selling products in the U. S. bearing the name " LGD- 4033, " which is the name previously used by Ligand to refer to VK5211, without authority from either us or Ligand, and we may experience other potential intellectual property infringement in the future. In addition, in December 2022, we filed suit against Ascletis Bioscience Co., Ltd., Gannex Pharma Co., Ltd., Ascletis Pharmaceuticals Co., Ltd., Ascletis Pharma Inc., and Jinzi Jason Wu, or the Ascletics Defendants, in the Southern District of California, San Diego division, alleging, among other things: (1) violation of the Defend Trade Secrets Act; (2) violation of the California Uniform Trade Secrets Act; (3) breach of contract; (4) breach of the implied covenant of good faith and fair dealing; and (5) tortious interference with contract. In a related action, we also filed suit against the same Ascletis Defendants in the International Trade Commission **, or the ITC,** for unlawful and unfair methods of competition **. On October 3, 2024, the ITC' s Chief Administrative Law Judge issued a Notice of his determination that the Ascletis Defendants misappropriated our trade secrets and engaged in discovery misconduct, warranting monetary and non- monetary sanctions** . Lawsuits to protect our intellectual property rights can be time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the biopharmaceutical industry generally. Such litigation or proceedings could increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities. In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. In addition, our licensed patents and patent applications, and patents and patent applications that we may apply for, own or license in the future, could face other challenges, such as interference proceedings, opposition proceedings, re- examination proceedings and other forms of post- grant review. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our licensed patents and patent applications and patents and patent applications that we may apply for, own or license in the future. Any of these challenges, regardless of their success, would likely be time- consuming and expensive to defend and resolve and would divert our management and scientific personnel' s time and attention. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the market price of our common stock. Changes in U. S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is costly, time- consuming and inherently uncertain. For example, on September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law. The Leahy- Smith Act included a number of significant changes to U. S. patent law, including provisions that affect the way patent applications will be prosecuted and that may also affect patent litigation. In particular, under the Leahy- Smith Act, the United States transitioned in March 2013 to a " first to file " system in which the first inventor to file a patent application is typically entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post- grant proceedings, including opposition,

derivation, reexamination, inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. In addition, the U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary patent system was introduced, which will significantly impact European patents, including those granted before the introduction of the system. Under the unitary patent system, after a European patent is granted, the patent proprietor can request unitary effect, thereby getting a European patent with unitary Effect, or a Unitary Patent. Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court, or the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of the new unitary patent system. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on drug candidates throughout the world would be prohibitively expensive. Competitors may use our licensed and owned technologies in jurisdictions where we have not licensed or obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain or license patent protection, but where patent enforcement is not as strong as that in the U. S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our licensed patents and future patents we may own, or marketing of competing products in violation of our proprietary rights generally. Further, 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 U. S. As a result, we may encounter significant problems in protecting and defending our licensed and owned intellectual property both in the U. S. and abroad. For example, China, where we currently have a number of licensed patents and licensed and owned patent applications, currently affords less protection to a company' s intellectual property than some other jurisdictions. As such, the lack of strong patent and other intellectual property protection in China may significantly increase our vulnerability regarding unauthorized disclosure or use of our intellectual property and undermine our competitive position. Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. In those countries, as of December 31, ~~2023~~ **2024** , we had several licensed and owned patents and several licensed and owned patent applications and may have limited remedies if such patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of such patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. We may be unable to adequately prevent unauthorized disclosure of trade secrets and other proprietary information. In order to protect our proprietary and licensed technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, manufacturers, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent unauthorized disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. For example, in our suit against the Ascletis Defendants that we filed in the Southern District of California, San Diego division, in December 2022, we brought claims related to breach of confidential disclosure agreements. There can be no assurance that we will be successful in this suit. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We employ individuals who were previously employed at other biopharmaceutical companies. Although we have no knowledge of any such claims against us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. To date, none of our employees have been subject to such claims. We may be subject to claims challenging the inventorship of our licensed patents, any future patents we may own and other intellectual property. Although we are not currently experiencing any claims challenging the inventorship of our licensed patents or our licensed or owned intellectual property, we may in the future

be subject to claims that former employees, collaborators or other third parties have an interest in our licensed patents or other licensed or owned intellectual property as an inventor or co- inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. If we do not obtain additional protection under the Hatch- Waxman Amendments and similar foreign legislation extending the terms of our licensed patents and any future patents we may own, our business, financial condition and results of operations may be materially and adversely affected. Depending upon the timing, duration and specifics of FDA regulatory approval for our drug candidates, one or more of our licensed U. S. patents or future U. S. patents that we may license or own may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. This period is generally one- half the time between the effective date of an investigational new drug application (falling after issuance of the patent), and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA. The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain earlier approval of competing products, and our ability to generate revenues could be materially adversely affected. Risks Relating to Ownership of Our Common Stock The market price of our common stock may be highly volatile. The trading price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following: • any delay in filing an NDA for any of our drug candidates and any adverse development or perceived adverse development with respect to the FDA' s review of that NDA; • adverse results or delays in clinical trials, if any; • significant lawsuits, including patent or stockholder litigation; • inability to obtain additional funding; • failure to successfully develop and commercialize our drug candidates; • changes in laws or regulations applicable to our drug candidates; • inability to obtain adequate product supply for our drug candidates, or the inability to do so at acceptable prices; • unanticipated serious safety concerns related to any of our drug candidates; • adverse regulatory decisions; • introduction of new products or technologies by our competitors; • failure to meet or exceed drug development or financial projections we provide to the public; • failure to meet or exceed the estimates and projections of the investment community; • the perception of the biopharmaceutical industry by the public, legislatures, regulators and the investment community; • announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our licensed and owned technologies; • additions or departures of key scientific or management personnel; • changes in the market valuations of similar companies; • general economic and market conditions and overall fluctuations in the U. S. equity market; • public health emergencies such as the COVID- 19 pandemic; • sales of our common stock by us or our stockholders in the future; and • trading volume of our common stock. In addition, the stock market, in general, and small 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. Further, a decline in the financial markets and related factors beyond our control may cause our stock price to decline rapidly and unexpectedly. An active trading market for our common stock may not be sustained, and you may not be able to resell your common stock at a desired market price. If no active trading market for our common stock is sustained, you may be unable to sell your shares when you wish to sell them or at a price that you consider attractive or satisfactory. The lack of an active market may also adversely affect our ability to raise capital by selling securities in the future, or impair our ability to acquire or in- license other drug candidates, businesses or technologies using our shares as consideration. Our management owns a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. As of December 31, ~~2023~~ **2024**, our executive officers, directors and 5 % or greater stockholders beneficially owned ~~19~~ **28**. ~~9~~ **3** % of our common stock. Therefore, our executive officers, directors and 5 % or greater stockholders have the ability to influence us through this ownership position. This concentration of stock ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. As a result, these stockholders, if they acted together, could materially influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. These stockholders may be able to determine all matters requiring stockholder approval. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders. This may also 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 and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock. ~~We are no longer a " smaller reporting company " within the meaning of the Securities Act of 1933, as amended, and as a result we are subject to~~

~~certain enhanced disclosure requirements which will require us to incur significant expenses and expend time and resources. We are no longer a " smaller reporting company, " as of January 1, 2024 and, as a result, we are or will be required to comply with various disclosure and compliance requirements that did not previously apply, such as the auditor attestation requirements of Section 404 (b) of the Sarbanes- Oxley Act of 2002, as amended, or the Sarbanes- Oxley Act, the requirement that we hold a nonbinding advisory vote on executive compensation and obtain shareholder approval of any golden parachute payments not previously approved, the requirement to provide full and more detailed executive compensation disclosure and the reduction in the amount of time for filing our periodic and annual reports. Compliance with these additional requirements increases our legal and financial compliance costs and causes management and other personnel to divert attention from operational and other business matters to these additional public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to delisting proceedings by the stock exchange on which our common shares are listed, or sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. We are not required to reflect the change in our smaller reporting company status and comply with the increased disclosure obligations until our quarterly report for the quarter ending March 31, 2024, the first quarter in our fiscal year ending December 31, 2024. We will need to reassess, as of June 30, 2024, whether we will continue to qualify as a large accelerated filer for filings beyond the fiscal year ending December 31, 2024.~~ Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes- Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes- Oxley Act, could have a material adverse effect on our business and share price. ~~During~~ **Commencing with** the fiscal year **ended** ~~2023, our management was required to report, on a quarterly basis, on the effectiveness of our internal control over financial reporting. Commencing with the fiscal year ending~~ December 31, 2023, in addition to our management' s report on the effectiveness of our internal controls over financial reporting, our independent registered public accounting firm **became** ~~will be~~ required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 **. In addition, commencing with the fiscal year 2024, our management became required to report, on a quarterly basis, on the effectiveness of our internal control over financial reporting** . The rules governing the standards that must be met for our management and our independent registered public accounting firm to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. In connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies or material weaknesses that we may not be able to remediate in time to meet the deadline imposed by the Sarbanes- Oxley Act for compliance with the requirements of Section 404. In addition, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation in connection with the attestation provided by our independent registered public accounting firm. Failure to achieve and maintain an effective internal control environment could have a material adverse effect on our business, financial condition and results of operations and could limit our ability to report our financial results accurately and in a timely manner. As a result of operating as a public company, we may incur significantly increased costs and our management and other personnel will be required to devote substantial time to new compliance initiatives. As a public company and particularly **since becoming** ~~after December 31, 2023, when we ceased to be a " smaller reporting company " and " non- accelerated filer, " and became~~ a " large accelerated filer " **as of December 31** , **2023,** we **have incurred and** expect **to continue** to incur additional significant legal, accounting and other expenses. In addition, the Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010, or the Dodd- Frank Act, as well as rules subsequently implemented by the SEC and The Nasdaq Stock Market LLC have imposed various requirements on public companies. There are significant corporate governance and executive compensation related provisions in the Dodd- Frank Act that require the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. We have a small management team that, along with other personnel, will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such insurance coverage. As a publicly traded company, we have incurred and will incur legal, accounting and other expenses associated with the SEC reporting requirements applicable to a company whose securities are registered under the Exchange Act, as well as corporate governance requirements, including those under the Sarbanes- Oxley Act, the Dodd- Frank Act and other rules implemented by the SEC and The Nasdaq Stock Market LLC. In addition, we expect that we will need to hire additional personnel in our finance department to help us comply with the various requirements applicable to public companies. The expenses incurred by public companies generally to meet SEC reporting, Sarbanes- Oxley Act compliance, finance and accounting and corporate governance requirements have been increasing in recent years as a result of changes in, and the adoption of, new rules and regulations applicable to public companies. If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline. The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline. Sales of a substantial number of shares of our common stock in the public market by our existing stockholders or future

issuances of our common stock or rights to purchase our common stock, could cause our stock price to fall. Sales of a substantial number of shares of our common stock by our existing stockholders in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. Our management will continue to have broad discretion over the use of the proceeds we received from our prior financings and available cash, and might not apply the proceeds in ways that increase the value of your investment. Our management will continue to have broad discretion to use the net proceeds from our prior financings and available cash and you will be relying on the judgment of our management regarding the application of these proceeds. Our management might not apply the proceeds in ways that ultimately increase the value of your investment and the failure by our management to apply these proceeds effectively could harm our business. Because of the number and variability of factors that will determine our use of these remaining net proceeds, their ultimate use may vary substantially from their currently intended use. If we do not invest or apply these net proceeds in ways that enhance stockholder value, we may fail to achieve the expected financial results, which could cause our stock price to decline. We are at risk of securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business, financial condition and results of operations. Our ability to use our net operating loss carryforwards may be subject to certain limitations. **At** ~~As of~~ December 31, ~~2023~~ **2024**, we had approximately $ ~~98~~ **157**. ~~7~~ **8** million of federal net operating loss carryforwards, of which $ 17. 8 million will begin to expire in 2032 and the remaining $ ~~80~~ **140**. ~~9~~ **0** million of which can be carried forward indefinitely. We have $ ~~79~~ **109**. ~~9~~ **6** million of state net operating loss carryforwards that will begin to expire in 2034. Our ability to utilize our federal net operating loss carryforwards may be limited under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code. In the event of an " ownership change, " Section 382 imposes an annual limitation on the amount of post- ownership change taxable income that may be offset with pre-ownership change net operating losses of the loss corporation experiencing the ownership change. An " ownership change " is defined by Section 382 as a cumulative change in ownership of our company of more than 50 % within a three- year period. Additionally, we have determined that our underwritten public offering of common stock completed in February 2018 resulted in an " ownership change " of us. However, as of December 31, ~~2023~~ **2024**, there is no limitation on the federal and state net operating losses. In addition, current or future changes in our stock ownership may trigger an " ownership change, " some of which may be outside our control. Accordingly, our ability to utilize our net operating loss carryforwards to offset federal taxable income, if any, will likely be limited by Section 382, which could potentially result in increased future tax liability to us **. Changes in tax laws could adversely affect our business and financial condition. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Trump administration has proposed various U. S. federal tax law changes, which if enacted could have a material impact on our business, cash flows, financial condition or results of operations. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one- time charges, and could increase our future U. S. tax expense**. We may never pay dividends on our common stock so any returns would be limited to the appreciation of our stock. We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock. Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult or expensive for a third party to acquire us or change our board of directors or current management. Some provisions of our charter documents and Delaware law may have anti- takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include: • authorizing the issuance of " blank check " preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval; • limiting the removal of directors by the stockholders; • creating a classified board of directors; • providing that no stockholder is permitted to cumulate votes at any election of directors; • allowing the authorized number of our directors to be changed only by resolution of our board of directors; • prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; • requiring the approval of the holders of at least 66 2 / 3 % of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our charter documents; • eliminating the ability of stockholders to call a special meeting of stockholders; and • establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved in advance by our board of directors or ratified by our board of directors and certain of our stockholders. This provision could have the effect of delaying or preventing a change in control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or

merging with us. ~~The timing and amount of any repurchases under our stock repurchase program are subject to a number of uncertainties. On March 10, 2022, our board of directors authorized a stock repurchase program effective March 18, 2022, whereby we may purchase up to $ 50. 0 million in shares of our common stock over a period of up to two years, or the Repurchase Program. The Repurchase Program may be carried out at the discretion of a committee of our board of directors through open market purchases, one or more Rule 10b5- 1 trading plans, block trades and in privately negotiated transactions. The Repurchase Program may be suspended, modified or discontinued at any time, and we have no obligation to repurchase any amount of our common stock under the Repurchase Program. The Inflation Reduction Act of 2022, enacted on August 16, 2022, imposes a 1 % excise tax on net repurchases of shares by U. S. corporations whose stock is traded on an established securities market. The excise tax will be imposed on repurchases that occur after December 31, 2022. The imposition of the excise tax on repurchases of our shares will increase the cost to us of making repurchases and may cause us to reduce the number of shares repurchased pursuant to the Repurchase Program.~~ Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees. Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (3) any action asserting a claim against us or our directors, officers or employees arising pursuant to any provision of our amended and restated bylaws, our amended and restated certificate of incorporation or the DGCL, (4) any action asserting a claim against us or our directors, officers or employees that is governed by the internal affairs doctrine, or (5) any action to interpret, apply, enforce or determine the validity of our amended and restated bylaws or our amended and restated certificate of incorporation. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our amended and restated bylaws. This choice- of- forum provision may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. In addition, a stockholder that is unable to bring a claim in the judicial forum of its choosing may be required to incur additional costs in the pursuit of actions that are subject to these exclusive forum provisions, particularly if the stockholder does not reside in or near Delaware. Alternatively, if a court were to find this provision of our amended and restated bylaws inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations. **The timing and amount of any repurchases under our stock repurchase program are subject to a number of uncertainties. In February 2025, our board of directors authorized a stock repurchase program effective February 27, 2025, whereby we may purchase up to $ 250. 0 million in shares of our common stock over a period of up to two years, or the Repurchase Program. The Repurchase Program may be carried out at the discretion of a committee of our board of directors through open market purchases, one or more Rule 10b5- 1 trading plans, block trades and in privately negotiated transactions. The Repurchase Program may be suspended, modified or discontinued at any time, and we have no obligation to repurchase any amount of our common stock under the Repurchase Program.**