Risk Factors Comparison 2025-02-27 to 2024-03-21 Form: 10-K

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Set forth below are the risks that we believe are material to our investors and they should be carefully considered. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and other factors not presently known to us or that we currently believe are immaterial may affect our business, prospects, financial condition and results of operations if they occur. This section contains forward- looking statements. You should refer to the explanation of the qualifications and limitations on forward- looking statements beginning on page ii of this Annual Report on Form 10- K. Risks Related to Our Limited Operating History, Financial Position and Capital Requirements Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability. We commenced operations in 2017 and are a clinical- stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Since our inception in October 2017, we have devoted substantially all of our efforts to organizing and staffing our company, business planning, capital raising, establishing and maintaining our intellectual property portfolio, building our pipeline of product candidates, conducting drug discovery activities, undertaking preclinical studies, conducting early- stage clinical trials, **preparing for the potential commercialization of bitopertin, if approved,** and providing general and administrative support for these operations. We have not yet demonstrated our ability to successfully develop any product candidate, obtain regulatory approvals, manufacture a commercial **-** scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products. In addition, as our business grows, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We have incurred significant net losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. Our net losses were $ ~~76~~ **109** . 4 million and $ ~~46~~ **76** . ~~8~~ **4** million for the **years** ~~twelve months~~ ended December 31, **2024 and** 2023 ~~and 2022~~ , respectively. We had an accumulated deficit of $ ~~188~~ **298** . ~~6~~ **0** million as of December 31, ~~2023~~ **2024** . Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from **selling,** general and administrative costs associated with our operations. We expect our research and development expenses to increase significantly in connection with the commencement and continuation of clinical trials of our product candidates. In addition, if we obtain regulatory approval for our product candidates, we will incur significant sales, marketing and manufacturing expenses. We also will continue to incur additional costs associated with operating as a public company and expect to continue to incur significant and increasing operating losses over the next several years and for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. The amount of our future losses is uncertain and our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following: • the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners; • our ability to successfully open clinical trial sites and recruit and retain subjects for clinical trials and any delays caused by difficulties in such efforts; • our ability to obtain regulatory approval for our product candidates, and the timing and scope of any such approvals we may receive; • the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time; • the cost of manufacturing our product candidates and products, should they receive regulatory approval, which may vary depending on the quantity of production and the terms of our agreements with manufacturers; • our ability to attract, hire and retain qualified personnel; • expenditures that we will or may incur to develop additional product candidates; • the level of demand for our products should they receive regulatory approval, which may vary significantly; • the risk / benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates; • the changing and volatile U. S. and global economic environments, including as a result of public health crises; and • future accounting pronouncements or changes in our accounting policies. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. This variability and unpredictability could also result in us failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even if we have met any previously publicly stated guidance we may provide. We have no products approved for commercial sale and have not generated any revenue from product sales. Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated collaborative revenue from our product candidates and have not generated revenue from product sales, and do not expect to generate any revenue from the sale of products in the near

future. We do not expect to generate significant revenue unless and until we obtain regulatory approval of, and begin to sell, one or more of our product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to: • successfully complete our ongoing and planned preclinical studies for our current and future product candidates; • timely file and receive acceptance of our Investigational New Drug applications, or INDs, in order to commence our planned clinical trials or future clinical trials; • successfully enroll subjects in and complete, our ongoing and planned clinical trials; • initiate and successfully complete all safety and efficacy studies necessary to obtain U. S. and foreign regulatory approval for our product candidates; • successfully address the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if any; • timely file New Drug Applications, or NDAs, and ~~Biologic~~ **Biologics** License Applications, or BLAs, and receive regulatory approvals for our product candidates from the U. S. Food and Drug Administration, or the FDA, and comparable foreign regulatory authorities; • establish and maintain clinical and commercial manufacturing capabilities or make arrangements with third- party manufacturers for clinical supply and commercial manufacturing; • obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates; • launch commercial sales of our products, if and when approved, whether alone or in collaboration with others; • obtain and maintain acceptance of our products, if and when approved, by patients, the medical community and third- party payors; • position our product candidates to effectively compete with other therapies; • obtain and maintain healthcare coverage and adequate reimbursement; • enforce and defend intellectual property rights and claims; and • maintain a continued acceptable safety profile of our products following approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. **Our existing and any future indebtedness could adversely affect our ability to operate our business. In November 2024, we entered into a Loan and Security Agreement, or the Hercules Loan Agreement, with the lenders party thereto, or the Lenders, and Hercules Capital, Inc., as administrative agent and collateral agent, or the Agent. The Hercules Loan Agreement provides for up to $ 200. 0 million of senior secured term loans, or the Term Loan, available to us in multiple tranches. The Term Loan will mature on December 1, 2029. Our obligations under the Hercules Loan Agreement are secured, subject to customary permitted liens and other agreed- upon exceptions, by a first- priority perfected security interest in all of our tangible and intangible assets, other than intellectual property. The Hercules Loan Agreement contains customary affirmative and negative covenants that could prevent us from taking certain actions without the consent of the Lenders. These covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our stockholders. Affirmative covenants include, among others, a financial covenant requiring us to maintain a minimum amount of qualified cash. Negative covenants include, among others: restrictions on transferring any part of our business or intellectual property; incurring additional indebtedness; engaging in mergers or acquisitions; paying dividends or making other distributions; making investments; and creating other liens on our assets, in each case subject to customary exceptions. The Hercules Loan Agreement also contains customary events of default, including the occurrence of a Material Adverse Effect (as defined in the Hercules Loan Agreement), and failure to make payments when due or comply with other covenants therein.** We ~~will~~ **intend to satisfy our current and future debt service obligations with our then- existing cash and cash equivalents. However, we may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under Hercules Loan Agreement or any other debt instruments. Upon the occurrence and continuance of an event of default, the Lenders may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Any declaration by the Lenders of an event of default would therefore significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. We may** need to raise substantial additional funding. If we are unable to raise capital when needed or on terms acceptable to us, we may be forced to delay, reduce or eliminate some of our product development programs or commercialization efforts. The development of pharmaceutical products is capital- intensive. We are currently advancing our hematologic disease programs through preclinical and clinical development. We expect our expenses to significantly increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate and complete clinical trials of, and seek regulatory approval for, our product candidates. In addition, depending on the status of regulatory approval or, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We may also need to raise additional funds sooner if we choose to pursue additional indications and / or geographies for our current or future product candidates or otherwise expand more rapidly than presently anticipated. Furthermore, we expect to **continue to** incur ~~additional~~ costs associated with operating as a ~~newly-~~ public company. Accordingly, we ~~will~~ **may** need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate certain of our research and development programs or future commercialization efforts. We believe that **our** ~~we have~~ cash ~~and~~ **,** cash equivalents ~~that~~ **and marketable securities, including the net proceeds of our January 2025 underwritten public offering,** will enable us to fund operating expenses and capital expenditure requirements ~~well~~ into ~~2026~~ **2028 , without taking into account any potential net cash inflows from bitopertin or any other marketed product, if approved during such period** . However, we have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than expected. Our future capital requirements will depend on and could increase significantly as a result of many factors, including: • the timing and progress of preclinical and clinical development activities; • the number and scope of preclinical and clinical programs we decide to pursue; • our ability to raise additional funds **to the extent** necessary to complete clinical development of and commercialize our product candidates; •

our ability to establish new and maintain existing licensing or collaboration arrangements and the progress of the development efforts of third parties with whom we may enter into such arrangements; • our ability to maintain our current research and development programs and to establish new programs; • the successful initiation, enrollment and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority; • the receipt and related terms of regulatory approvals from applicable regulatory authorities for any product candidates; • the availability of raw materials for use in production of our product candidates; • establishing agreements with third- party manufacturers for supply of product candidate components for our clinical trials; • our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally; • our ability to protect our other rights in our intellectual property portfolio; • commercializing product candidates, if and when approved, whether alone or in collaboration with others; • obtaining and maintaining third- party insurance coverage and adequate reimbursement for any approved products; and • the potential additional expenses attributable to adjusting our development plans (including any supply related matters) to any public health crises. Identifying potential product candidates and conducting preclinical development testing and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of products that **may take longer than** we **anticipate** ~~do not expect~~ to ~~be~~ **become** commercially available ~~for several years~~, if **they become commercially available** at all. Accordingly, we ~~will~~ **may** need to continue to rely on additional financing to achieve our business objectives. Any additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our product candidates. Disruptions in the financial markets in general may make equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to obtain funding on a timely basis or on acceptable terms, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product that has received regulatory approval or be unable to expand our operations or otherwise capitalize on our business opportunities as desired, which could materially affect our business, financial condition and results of operations. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, we can generate substantial product revenue, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. ~~We~~ **Other than up to $ 80. 0 million of additional advances that may be drawn at our option under the Hercules Loan Agreement, we** do not have any committed external source of funds. The terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted, and the terms of those securities may include liquidation or other preferences that may materially adversely affect your rights as a common stockholder. **Additional** ~~Debt~~ **debt** financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, acquiring, selling or licensing intellectual property rights, and making capital expenditures, declaring dividends or other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to meet certain milestones in connection with debt financing and the failure to achieve such milestones by certain dates may force us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us which could have a material adverse effect on our business, operating results and prospects. We also could be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable. If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, grant licenses on terms that may not be favorable to us or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourself, any of which may have a material adverse effect on our business, operating results and prospects. Risks Related to the Discovery and Development of Our Product Candidates We have ~~only successfully completed one~~ **not yet progressed any product candidates into a** Phase ~~1~~ **3** clinical trial and may be unable to successfully complete any additional clinical trials for any product candidates we develop. Certain of our programs are still in preclinical development and may never advance to clinical development. We **currently** have ~~completed~~ **only three product candidates in clinical development,** ~~one~~ **none of which has yet progressed into a** Phase ~~1~~ **3** clinical trial ~~and~~ **. As such, we** have not yet demonstrated our ~~continued~~ ability to successfully complete ~~clinical trials, including~~ large- scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful commercialization. ~~Our~~ **The majority of our** programs are still in preclinical and early **to mid- stage** clinical development. Our clinical programs may not advance to the next stage of clinical development, and our preclinical programs may never advance to clinical development or through clinical development, as applicable ~~. We currently only have three product candidates in clinical development. In July 2022, we initiated BEACON, a Phase 2 open- label, parallel- dose clinical trial of bitopertin in EPP and XLP patients that is being conducted at sites in Australia. Separately, in October 2022, we initiated AURORA, a Phase 2, randomized, double- blind, placebo- controlled clinical trial of bitopertin in EPP patients that is being conducted at sites in the United States. We completed our Phase 1 clinical trial of DISC- 0974 in healthy volunteers. We initiated a Phase 1b / 2 clinical trial of DISC- 0974 in June 2022 in patients with anemia of MF, and initiated a separate Phase 1b / 2 clinical trial in February 2023 in patients with non- dialysis dependent CKD and anemia. We initiated a Phase 1 clinical trial of DISC- 3405 in healthy volunteers in October 2023~~. We may not initiate any

clinical trial of our product candidates until we have submitted an IND to the FDA or comparable submissions with equivalent regulatory authorities and received regulatory clearance. We may not be able to submit INDs or other regulatory filings for bitopertin or any of our other product candidates on the timelines we expect, if at all. For example, we may experience manufacturing delays or other delays with IND- enabling studies. Moreover, we cannot be sure that submission of regulatory filings with the FDA or other regulatory authorities will result in such regulatory authorities allowing clinical trials to begin on a timely basis or at all, or that, once begun, such trials will be completed on schedule, if at all, or that issues will not arise that require us to revise, postpone, suspend or terminate our clinical trials. For example, we filed an IND in April 2022 with the FDA to initiate the AURORA Phase 2 trial of bitopertin in EPP patients, but the FDA initially placed the initiation of this trial on clinical hold; we received clearance to initiate the study in July 2022 after the study design was finalized with the FDA, and we initiated the study in October 2022. Commencing any of our clinical trials is subject to finalizing the trial design based on discussions with the FDA and other regulatory authorities. Any guidance we receive from the FDA or other regulatory authorities is subject to change. These regulatory authorities could change their position, including on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or result in the composition of stricter approval conditions than currently expected. For a further example, we relied on the data package generated by F. Hoffmann- La Roche Ltd. and Hoffmann- La Roche Inc., or collectively, Roche, to support our IND submission for bitopertin to initiate our AURORA Phase 2 clinical trial in patients with EPP, as well as our submission of an application with the Australian Therapeutic Goods Administration, or TGA, for our BEACON Phase 2 clinical trial in patients with EPP or XLP, and it is possible that the FDA or TGA, as applicable, may require us to conduct additional preclinical studies to support a future marketing application of bitopertin. Successful completion of our clinical trials is a prerequisite to submitting an NDA or a BLA to the FDA, a Marketing Authorisation Application, or MAA, to the European Medicines Agency, or EMA, or other marketing applications to regulatory authorities in other jurisdictions, for each product candidate and, consequently, the regulatory approval of each product candidate. A single well- controlled clinical trial may not be sufficient for approval. In general, the FDA requires two well- controlled clinical trials to support registration of a new drug or biologic. Exceptions may be made in cases of a severe disease with few treatment options, and in principle this exception may appear applicable to many of the diseases that we seek to treat, such as EPP, XLP, anemia of MF, DBA and others. Nonetheless, the FDA and other regulators may always require additional clinical trials to support regulatory approval. If we are required to conduct additional preclinical studies or clinical trials or other testing of our product candidates beyond those that are currently contemplated, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: • be delayed in obtaining regulatory approval for our product candidates; • not obtain regulatory approval at all; • obtain regulatory approval for indications or patient populations that are not as broad as intended or desired; • continue to be subject to post- marketing testing requirements; or • experience having the product removed from the market after obtaining regulatory approval. Our programs are focused on the development of therapeutics for patients with hematologic diseases, which is a rapidly evolving area of science, and the approach we are taking to discover and develop product candidates is novel and may never lead to approved or marketable products. The discovery and development of therapeutics for patients with hematologic diseases is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although we believe, based on our preclinical work **and clinical results to date,** that our programs have the potential to provide disease- modifying therapies, **future** clinical results ~~in patients~~ may not confirm this hypothesis or may only confirm it for certain alterations or certain indications. The patient populations for our product candidates are limited to those with specific hematologic diseases. We cannot be certain that the patient populations for each specific disease will be large enough to allow us to successfully obtain approval **for** and commercialize our product candidates and achieve profitability. Clinical product development involves a lengthy and expensive process, with an uncertain outcome. Our preclinical studies and future and ongoing clinical trials may not be successful. Currently, ~~all~~ **the majority** of our programs are in preclinical and early **to mid-stage** clinical development. It is impossible to ~~predict~~ **know** when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates or the safety, purity and potency of our biological product candidates in humans. There is no guarantee that our product candidates will advance in accordance with the timelines we anticipate, if at all. Clinical testing is expensive, difficult to design and implement, can take many years to complete and outcomes are uncertain. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim, top- line, initial or preliminary results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their product candidates. Our preclinical studies and future and ongoing clinical trials may not be successful. Additionally, some of the clinical trials we conduct **, such as our completed BEACON Phase 2 clinical trial of bitopertin and our ongoing Phase 2 clinical trial of DISC- 0974,** may be open- label in study design and may be conducted at a limited number of clinical sites on a limited number of patients. An " open- label " clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open- label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open- label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open- label clinical trials are aware when they are receiving treatment. Open- label clinical trials may be subject to a " patient bias " where patients perceive their

symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open- label clinical trials may be subject to an " investigator bias " where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open- label clinical trial may not be predictive of future clinical trial results when studied in a controlled environment with a placebo or active control. In May 2021, we entered into a license agreement with Roche, or the Roche Agreement, pursuant to which, among other things, Roche granted us an exclusive and sublicensable (subject to Roche' s consent, except with respect to affiliates) worldwide license under certain of Roche' s patent rights and know- how to develop and commercialize bitopertin. Although bitopertin was originally evaluated by Roche in over 4, 000 individuals, Roche did not evaluate bitopertin in EPP or XLP, so the safety data generated from Roche' s clinical trials of bitopertin may not be predictive or indicative of the results of our clinical trials. Regulatory authorities may also raise questions regarding the transition in the future from Roche- manufactured drug substance to drug substance manufactured by us or another party, and we may be required to conduct comparability assessments, which could result in delays in development and additional costs. We may face similar challenges with respect to our other product candidates, for which preclinical results may not be indicative or predictive of future clinical trial results. Because we are developing some of our product candidates for the treatment of diseases in which there is little clinical experience and, in some cases, using new endpoints or methodologies, the FDA or other regulatory authorities may not consider the endpoints of our clinical trials to predict or provide clinically meaningful results. Many of our product candidates are designed to treat diseases for which there are few available therapeutic options. For example, in the United States there are currently no therapies approved to treat anemia of MF and there is only one approved therapy to treat EPP. As a result, the design and conduct of clinical trials of product candidates for the treatment of these diseases may take longer, be more costly or be less effective as part of the novelty of development in these diseases. In some cases, we may use new or novel endpoints or methodologies. The FDA or other regulatory authorities may not consider the endpoints of our clinical trials to be validated or clinically meaningful and we may need to conduct proof- of- concept studies or additional work to refine our endpoints and inform the design of future studies before initiating pivotal studies of our product candidates. Even if applicable regulatory authorities do not object to our proposed endpoints in an earlier stage clinical trial, such regulatory authorities may require evaluation of additional or different clinical endpoints in later- stage clinical trials. Even if the FDA does find our clinical trial success criteria to be sufficiently supported and clinically meaningful at the time, we may not achieve the pre- specified endpoint to a degree of statistical significance in any pivotal or other clinical trials we may conduct for our product candidates. Further, even if we do achieve the pre- specified criteria, our trials may produce results that are unpredictable or inconsistent with the results of the more traditional efficacy endpoints in the trial. The FDA also could change its view or give overriding weight to other efficacy endpoints over a primary endpoint, even if we achieve statistically significant results on that primary endpoint, if for example we do not do so on our secondary efficacy endpoints. The FDA also weighs the benefits of a product candidate against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of approval. Other regulatory authorities in Europe and other countries may make similar findings with respect to these endpoints. Interim, top- line, initial and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to confirmation, audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose interim, top- line, initial or preliminary data from our clinical trials, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. For example, we announced ~~top- line results from the Phase 1 DISC- 0974 clinical trial in June 2022 and initial data from our Phase 2 BEACON clinical trial of bitopertin in June 2023. We also announced updated data from our Phase 2 BEACON clinical trial of bitopertin and~~ initial data from our Phase 1b / 2 DISC- 0974 ~~trials~~ **trial** in patients with anemia of MF **in December 2023, June 2024,** and **December 2024, and from our Phase 1b DISC- 0974 trial in** patients with anemia and NDD- CKD in December 2023 **and October 2024. We also announced initial data from the SAD portion of the Phase 1 clinical trial of DISC- 3405 in healthy volunteers in June 2024** . We also may make assumptions, estimations, calculations and conclusions as part of our analyses of data, and may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, top- line, initial or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, top- line, initial and preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim, top- line, initial and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim, top- line, initial or preliminary data we previously published. As a result, interim, top- line, initial and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim, top- line, initial or preliminary data and final data could significantly harm our business prospects and may cause the price of our common stock to fluctuate or decline. Further, regulatory agencies and others, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could adversely impact the potential of the particular program, the likelihood of obtaining regulatory approval of the particular product candidate, commercialization of any approved product and the business prospects of the company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top- line, initial or preliminary data that we report differs from actual results, or if regulatory authorities or others, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be significantly impaired, which could materially harm our business, operating results, prospects or financial condition. We may incur additional costs or experience delays in initiating or completing, or ultimately be unable to complete,

the development and commercialization of our product candidates. We may experience delays in initiating or completing our preclinical studies or clinical trials, including as a result of delays in obtaining, or failure to obtain, the FDA' s authorization to initiate clinical trials under future INDs. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will not require redesign, will enroll an adequate number of subjects on time, or will be completed on schedule, if at all. We may experience numerous unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive regulatory authorizations, regulatory approval or commercialize our product candidates, including: • we may receive feedback from regulatory authorities that requires us to modify the design or implementation of our preclinical studies or clinical trials or to delay or terminate a clinical trial; • regulators or institutional review boards, or IRBs, or ethics committees may delay or may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective clinical research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • preclinical studies or clinical trials of our product candidates may fail to show safety or efficacy or otherwise produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, or we may decide to abandon product research or development programs; • preclinical studies or clinical trials of our product candidates may not produce differentiated or clinically significant results across indications; • the number of patients required for clinical trials of our product candidates may be larger than anticipated, enrollment in these clinical trials may be slower than anticipated or participants may drop out of these clinical trials or fail to return for post- treatment follow- up at a higher rate than anticipated; • our third- party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, be unable to provide us with sufficient product supply to conduct or complete preclinical studies or clinical trials, fail to meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators; • we may elect to, or regulators or IRBs or ethics committees may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our clinical trials are being exposed to unacceptable health risks; • the cost of clinical trials of our product candidates may be greater than anticipated; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate, and any transfer of manufacturing activities may require unforeseen manufacturing or formulation changes; • our product candidates may have undesirable side effects or other unexpected characteristics, causing us, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other hematologic disease therapies that raise safety or efficacy concerns about our product candidates; • any future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us; and • regulators may revise the requirements for approving our product candidates, or such requirements may not be as anticipated. We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions at which such trials are being conducted or by the FDA or other regulatory authorities, or if the Data Safety Monitoring Board, or DSMB, for such trial recommends suspension or termination of the trial. Such authorities may impose or recommend such a suspension or termination or clinical hold due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, adverse findings upon an inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, we filed an IND in April 2022 with the FDA to initiate the AURORA Phase 2 trial of bitopertin in EPP patients, but the FDA initially placed the initiation of this trial on clinical hold; we received clearance to initiate the study in July 2022 after the study design was finalized with the FDA and initiated the study in October 2022. 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. Further, the FDA may disagree with our clinical trial design or our interpretation of data from clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. Moreover, principal investigators for our current and future clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site, and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates. Our product development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our future clinical trials will begin as planned, or whether any of our current or future clinical trials will need to be restructured or will be completed on schedule, if at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may significantly harm our business, operating results, financial condition and prospects. If we experience delays or difficulties in the enrollment of patients in 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 comparable foreign regulatory authorities, or as needed to provide appropriate statistical power for a

given trial. In particular, because we are focused on patients with specific rare hematologic diseases for the development of our product candidates, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. We may experience difficulties with identifying specific patient populations for any defined trial cohorts. The patient eligibility criteria defined in our trial protocols may limit the patient populations eligible for our clinical trials. We will also rely on the willingness and ability of clinicians to screen their patients, such as for specific genetic hematologic conditions, to indicate which patients may be eligible for enrollment in our clinical trials. In addition, some of our competitors have ongoing clinical trials for product candidates that are intended to treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may choose instead to enroll in clinical trials of our competitors' product candidates. Additionally, the process of finding patients may prove costly. We also may not be able to identify, recruit or enroll a sufficient number of patients to complete our clinical trials because of the small patient populations with rare hematologic diseases, the perceived risks and benefits of the product candidates under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. Patient enrollment may be affected by other factors, including: • the severity of the disease under investigation; • the efforts to obtain and maintain patient consents and facilitate timely enrollment in clinical trials; • the ability to monitor patients adequately during and after treatment; • the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion; • the ability to recruit clinical trial investigators with the appropriate competencies and experience; • reporting of the preliminary results of any of our clinical trials; and • factors we may not be able to control, including the impacts of any public health crises, that may limit patients, principal investigators or staff or clinical site availability. Results from early preclinical studies and clinical trials of our programs and product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of our programs and product candidates. If we cannot replicate the results from earlier preclinical studies and clinical trials of our programs and product candidates in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates. Any results from early preclinical studies and clinical trials of bitopertin, DISC- 0974, DISC- 0998, DISC- 3405 or our other product candidates or programs may not necessarily be predictive of the results from later preclinical studies and clinical trials. For example, **we have announced positive initial data from** ~~DISC- 0974 has undergone testing in healthy volunteers,~~ a Phase 1b / 2 clinical trial ~~in patients with anemia~~ of **DISC-0974** ~~MF was initiated in June 2022 and a separate Phase 1b / 2 clinical trial~~ in patients with non- dialysis dependent CKD and anemia ~~was initiated in February 2023~~. However, there can be no assurance that DISC- 0974 will achieve the desired effects in ~~these~~ **this** ~~indications~~ **indication**. Additionally, we ~~initiated~~ **announced positive results from** a Phase 1 clinical trial of DISC-3405 in healthy adult volunteers in ~~October~~ **December** ~~2023~~ **2024**, which may not be indicative or predictive of future clinical trial results. Similarly, even if we are able to complete our planned preclinical studies and clinical trials of our product candidates according to our current development timeline, the results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results. Many companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials after achieving positive results in early- stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval. Our clinical trials or those of our future collaborators may reveal significant adverse events not seen in prior preclinical studies or clinical trials and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates. Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates regulated as drugs are safe and effective and our product candidates regulated as biologics are safe, pure and potent for use in each target indication. Clinical testing is expensive and can take many years to complete, and outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process. Because **the majority of** our programs and product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials also may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. For example, Roche had previously developed bitopertin as a potential therapy for certain symptoms of schizophrenia and obsessive- compulsive disorder, but discontinued the program for lack of efficacy in those indications after completing over 30 clinical trials in over 4, 000 individuals. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our programs and product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented from, or delayed in, obtaining regulatory approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment- related side effects could also affect patient recruitment or the ability of enrolled patients to complete

the trial or result in potential product liability claims. Further, our product candidates could cause undesirable side effects in clinical trials related to on- target toxicity. If on- target toxicity is observed, or if our product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. In addition, our product candidates could cause undesirable side effects that have not yet been observed. For example, bitopertin may demonstrate toxicities in patients with hematologic diseases not previously observed by Roche when it was studied in different indications. Many compounds that initially showed promise in early- stage testing have later been found to cause side effects that prevented further development of the compound. Most product candidates that commence clinical trials are never approved as products, and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development or regulatory approval of any of our product candidates. As is the case with many treatments for hematologic and rare diseases, it is likely that there may be side effects associated with the use of our product candidates. If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or development efforts of one or more product candidates altogether. We, the FDA or other applicable regulatory authorities, or an IRB may suspend or terminate clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Even if the side effects do not preclude the product from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, operating results, financial condition and prospects. Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval or discovery of unknown or unanticipated adverse effects on safety or efficacy. Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, which may result in uncertainty. We select programs for targets based on compelling biological rationale, including evidence of expected biological effects in humans. We explore new programs based on extensive preclinical data analysis which sometimes cannot predict efficacy or safety in humans. Regulatory approval of novel product candidates such as ours can be more expensive, riskier and take longer than for other, more well- known or extensively studied pharmaceutical or biopharmaceutical product candidates due to our and regulatory agencies' lack of experience with them. The novelty of the mechanism of action of any of our product candidates may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post- approval limitations or restrictions. The novel mechanism of action also means that fewer people are trained in or experienced with product candidates of this type, which may make it more difficult to find, hire and retain personnel for research, development and manufacturing positions. If our product candidates utilize a novel mechanism of action that has not been the subject of extensive study compared to more well- known product candidates, there is also an increased risk that we may discover previously unknown or unanticipated adverse effects during our preclinical studies and clinical trials. Our product candidates may achieve lower efficacy in patients than expected. Any such events could adversely impact our business prospects, operating results and financial condition. We **have conducted and** are currently conducting ~~a Phase 2~~ clinical ~~trial~~ **trials** for bitopertin in Australia and may in the future conduct additional clinical trials of our product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials. **We conducted** ~~In July 2022, we initiated~~ BEACON, ~~a~~ **our** Phase 2 open- label, parallel- dose clinical trial of bitopertin in EPP and XLP patients **,** ~~that is being conducted~~ at sites in Australia **. All participants in BEACON are eligible to participate in HELIOS, an open- label, long- term extension study of bitopertin in EPP and XLP patients, that we are also conducting in Australia. We are also planning to conduct APOLLO, a randomized, double- blind, placebo- controlled clinical trial of bitopertin in EPP and XLP patients, in Canada, Europe and Australia, as well as the United States** . We may in the future choose to conduct additional clinical trials of our product candidates outside the United States, including in Europe, Australia, or other foreign jurisdictions. The acceptance of trial data from clinical trials conducted outside the United States by the FDA may be subject to certain conditions. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practices, (ii) the trials were performed by clinical investigators of recognized competence and (iii) the data may be considered valid without the need for an on- site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials will be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority ~~, including the TGA~~ , will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time- consuming and delay aspects of our business plan, and which may result in our product candidates not receiving regulatory approval or clearance for commercialization in the applicable jurisdiction. Although we intend to explore other therapeutic opportunities in addition to the programs and product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional product candidates, our business could be materially harmed. Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require

substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and / or product candidates, yet fail to yield results for clinical development for a number of reasons, including: • the research methodology used may not be successful in identifying potential indications and / or product candidates; • potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective products; or • it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio. Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of 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 or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for **any of** our product candidates, we will not be able to commercialize, or will be delayed in commercializing, ~~our~~ **such** product candidates, and our ability to generate revenue will be materially impaired. Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. Before we can commercialize any of our product candidates, we must obtain regulatory approval. Currently, all of our product candidates are in discovery, preclinical or clinical development, and we have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. It is possible that our product candidates, including any product candidates we may seek to develop in the future, will never obtain regulatory approval. We have limited experience in filing and supporting the applications necessary to gain regulatory approvals and rely on third- party CROs and / or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use. In addition, regulatory authorities may find fault with our manufacturing process or facilities or that of third- party contract manufacturers. We may also face greater than expected difficulty in manufacturing our product candidates. The process of obtaining regulatory approvals, both in the United States and abroad, is expensive and often takes many years. If the FDA or a comparable foreign regulatory authority requires that we perform additional preclinical studies or clinical trials, approval may be delayed, if obtained at all. The length of such a delay varies substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. Changes in regulatory approval policies during the development period, changes in or enactment of additional statutes or regulations, or changes in regulatory review policies for each submitted NDA, BLA, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; • ~~We~~ **we** may not be able to enroll a sufficient number of patients in our clinical trials; • ~~We~~ **we** may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; • the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • ~~We~~ **we** may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; • the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, BLA or other submission or to obtain regulatory approval in the United States or elsewhere; • the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change such that our clinical data are insufficient for approval. Even if we were to obtain regulatory approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, thereby narrowing the commercial potential of the product candidate. In addition, regulatory authorities may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. If we experience delays in obtaining, or if we fail to obtain, approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired. A public health crisis, pandemic, epidemic, or outbreak of an infectious or highly contagious disease, may materially and adversely affect our business and financial results and could cause a disruption to the development of our product candidates. Public health crises

such as pandemics or similar outbreaks could adversely impact our business. The extent to which an outbreak of highly infectious or contagious diseases impacts our operations or those of our third- party partners, including our preclinical studies or clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of the outbreak, actions taken to contain the outbreak or mitigate its impact, and the direct and indirect economic effects of the outbreak and containment measures, among others. In addition, the patient populations that our product candidates target may be particularly susceptible to highly infectious or contagious diseases, which may make it more difficult for us to identify patients able to enroll in our current and future clinical trials and may impact the ability of enrolled patients to complete any such trials. Risks Related to Commercialization We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. The development and commercialization of new products in the biopharmaceutical and related industries is highly competitive. We compete in the segments of the pharmaceutical, biotechnology, and other related markets that develop therapies in the field of hematologic diseases. There are other companies focusing on developing therapies in the field of hematologic diseases. We also compete more broadly across the market for cost- effective and reimbursable treatments. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. **See " Business- Competition " for examples of the competition that our product candidates face.** Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future from segments of the pharmaceutical, biotechnology and other related markets. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. We believe principal competitive factors to our business include, among other things, our ability to successfully transition research programs into clinical development, ability to raise capital and the scalability of the platform, pipeline and business. Many of the companies that we compete against or which we may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. If these or other barriers to entry do not remain in place, other companies may be able to more directly or effectively compete with us. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their products sooner than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, level of generic competition and availability of reimbursement from government and other third- party payors. If the market opportunities for our programs and product candidates are smaller than we estimate or if any regulatory approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability could be materially adversely affected. The incidence and prevalence for the target patient populations of our programs and product candidates have not been established with precision. Our lead heme biosynthesis modulation product candidate, bitopertin, is an oral, selective inhibitor of GlyT1. We are initially focused on developing bitopertin for the treatment of EPP and XLP, which are both diseases marked by severe photosensitivity and damage to the hepatobiliary system caused by the accumulation of PPIX. ~~In July 2022, we initiated BEACON, a Phase 2 open- label, parallel- dose clinical trial of bitopertin in EPP and XLP patients that is being conducted at sites in Australia. Separately, in October 2022, we initiated AURORA, a Phase 2, randomized, double- blind, placebo- controlled clinical trial of bitopertin in EPP patients that is being conducted at sites in the United States.~~ We **are initially focused on developing** ~~initiated a Phase 1b / 2 clinical trial of~~ DISC- 0974 **for** ~~in June 2022 in the United States in patients with~~ anemia of MF **and anemia of** ~~, initiated a separate Phase 1b / 2 clinical trial in the February 2023 in patients with~~ non- dialysis dependent CKD ~~and anemia, and initiated a Phase 1 clinical trial of DISC- 3405 in healthy adult volunteers in October 2023~~ . We are initially focused on developing DISC- 3405 for the treatment of PV. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our programs and product candidates, are based on our estimates. The total addressable market opportunity will ultimately depend upon, among other things, the diagnosis criteria included in the final label, the indications for which our product candidates are approved for sale, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients with erythropoietic porphyria and anemias of inflammation for which our product candidates may be approved as treatment may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates,

which may prove to be the wrong choice and may adversely affect our business. If our current product candidates or any future product candidates do not achieve broad market acceptance, the revenue that we generate from our sales may be limited, and we may never become profitable. We have never commercialized a product candidate for any indication. Even if our current product candidates and any future product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third- party payors, and others in the medical community. If any product candidates for which we may obtain regulatory approval do not gain an adequate level of market acceptance, we may not generate significant revenue and may not become profitable or may be significantly delayed in achieving profitability. Market acceptance of our current product candidates and any future product candidates by the medical community, patients and third- party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients, and patients may be reluctant to switch, from existing therapies even when new and potentially more effective or safer treatments enter the market. If public perception is influenced by claims that the use of heme biosynthesis modulation therapies or hepcidin- targeted agents is unsafe, whether related to our or our competitors' products, our products may not be accepted by the general public or the medical community. Future adverse events in the hematologic diseases or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates. In the United States and markets in other countries, patients generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Efforts to educate the medical community and third- party payors on the benefits of our current product candidates and any future product candidates may require significant resources and may not be successful. If our current product candidates or any future product candidates are approved but do not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any of our current product candidates and any future product candidates will depend on a number of factors, including: • the efficacy of our current product candidates and any future product candidates; • the prevalence and severity of adverse events associated with our current product candidates and any future product candidates; • the clinical indications for which our product candidates are approved and the approved claims that we may make for the products; • limitations or warnings contained in the product' s FDA- approved labeling or those of comparable foreign regulatory authorities, including potential limitations or warnings for our current product candidates and any future product candidates that may be more restrictive than other competitive products; • changes in the standard of care for the targeted indications for our current product candidates and any future product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained; • the relative convenience and ease of administration of our current product candidates and any future product candidates; • the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies; • the availability of adequate coverage or reimbursement by third- party payors, including government healthcare programs such as Medicare and Medicaid and other healthcare payors; • the price concessions required by third- party payors to obtain coverage; • the willingness of patients to pay out- of- pocket in the absence of adequate coverage and reimbursement; • the extent and strength of our marketing and distribution of our current product candidates and any future product candidates; • the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved; • distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our current product candidates and any future product candidates or to which we agree as part of a Risk Evaluation and Mitigation Strategy, or REMS, or voluntary risk management plan; • the timing of market introduction of our current product candidates and any future product candidates, as well as competitive products; • our ability to offer our current product candidates and any future product candidates for sale at competitive prices; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the extent and strength of our third- party manufacturer and supplier support; • the approval of other new products; • adverse publicity about our current product candidates and any future product candidates or favorable publicity about competitive products; and • potential product liability claims. There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U. S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. ~~It is unclear what effect, if any, the American Rescue Plan will have on the number of covered individuals.~~ We may not be successful in addressing these or other factors that might affect the market acceptance of our product candidates. Failure to achieve widespread market acceptance of our product candidates would materially harm our business, financial condition and results of operations. Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post- market study requirements, marketing and labeling restrictions and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements. If the

FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, monitoring and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post- approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. For certain commercial prescription drug and biological products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. Additionally, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product' s ability to be marketed. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: • restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls; • manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation; • revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings; • imposition of a REMS which may include distribution or use restrictions; • requirements to conduct additional post- market clinical trials to assess the safety of the product; • clinical trial holds; • fines, warning letters or other regulatory enforcement action; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals; • product seizure or detention, or refusal to permit the import or export of products; and • injunctions or the imposition of civil or criminal penalties. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. **In addition, the U. S. Supreme Court' s July 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA' s regulations, policies and decisions may become subject to increasing legal challenges, delays, and / or changes.** If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. Risks Related to Our Reliance on Third Parties We rely on third parties to conduct our ~~Phase 2 clinical trials of bitopertin, Phase 1b / 2 clinical trials of DISC- 0974 and Phase 1 clinical trial of DISC- 3405 and expect to rely on third parties to conduct other~~ clinical trials for our product candidates, as well as potential investigator- sponsored clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed. We do not have the ability to independently conduct clinical trials. We ~~rely~~ **have relied on** and expect to continue to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support **our** clinical trials for our product candidates, including our ~~Phase 2~~ **planned APOLLO** clinical ~~trials~~ **trial** of bitopertin ~~, Phase 1b / 2 clinical trials of DISC- 0974~~ in **EPP** ~~patients with anemia of MF or non- dialysis dependent CKD~~ and **XLP** ~~anemia, our Phase 1 trial of DISC- 3405~~ , as well as any other product candidates that we develop. We may also rely on academic and private non- academic institutions to conduct and sponsor clinical trials relating to our product candidates, such as the ongoing clinical trial of bitopertin in DBA, which is being conducted by NIH under a collaborative research and development agreement. We will not control the design or conduct of any investigator- sponsored trials, and it is possible that the FDA or non- U. S. regulatory authorities will not view these investigator- sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. Such arrangements will likely provide us certain information rights with respect to the investigator- sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator- sponsored trials. However, we would not have control over the timing and reporting of the data from investigator- sponsored trials, nor would we own the data from the investigator- sponsored trials. If we are unable to confirm or replicate the results from the investigator- sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the first- hand knowledge we might have gained had the investigator- sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourself may be adversely affected. We rely and expect to continue to rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of our activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs or other third parties will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the

conduct of our clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution. We, our principal investigators and our CROs are required to comply with regulations, including GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or the EEA, and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we, our principal investigators or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with product candidates produced under current Good Manufacturing Practice, or cGMP, regulations. Our failure or the failure of our principal investigators or CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, significantly increase our expenditures and could also subject us to enforcement action. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government- sponsored database, ClinicalTrials. gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Although we designed our ongoing Phase 1b / 2 clinical trials of DISC-0974 ~~,~~ **and our** ongoing Phase 2 clinical ~~trials~~ **trial** of bitopertin, **are designing our planned APOLLO clinical trial of bitopertin** and ~~ongoing~~ **our planned** Phase ~~1~~ **2** clinical trial of DISC- 3405, and intend to design ~~the~~ **other** future clinical trials for our product candidates, these trials are or will be conducted by CROs and we expect CROs will conduct all of our future clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct future clinical trials also results in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may: • have staffing difficulties; • fail to comply with contractual obligations; • experience regulatory compliance issues; • undergo changes in priorities or become financially distressed; or • form relationships with other entities, some of which may be our competitors. These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the principal investigators or CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates or our development program may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our principal investigators or CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures. If any of our relationships with these third- party principal investigators or CROs terminate, we may not be able to enter into arrangements with alternative CROs. If principal investigators or CROs do not successfully carry out their contractual obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such principal investigators or CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed. We might not realize the anticipated benefits of our current collaborations with Mabwell or NIH, or any other collaborations we enter into in the future. Research, development, commercialization and / or strategic collaborations, including those that we have with Mabwell and NIH, are subject to numerous risks, which include the following: • collaborators may have significant control or discretion in determining the efforts and resources that they will apply to a collaboration, and might not commit sufficient efforts and resources or might misapply those efforts and resources; • we may have limited influence or control over the approaches to research, development and / or commercialization of product candidates in the territories in which our collaboration partners lead research, development and / or commercialization; • collaborators might not pursue research, development and / or commercialization of collaboration product candidates or might elect not to continue or renew research, development and / or commercialization programs based on preclinical studies and / or clinical trial results, changes in their strategic focus, availability of funding or other factors, such as a business combination that diverts resources or creates competing priorities; • collaborators might delay, provide insufficient resources to, or modify or stop research or clinical development for collaboration product candidates or require a new formulation of a product candidate for clinical testing; • collaborators with sales, marketing and distribution rights to one or more product candidates might not commit sufficient resources to sales, marketing and distribution or might otherwise fail to successfully commercialize those product candidates; • collaborators might not properly maintain or defend our intellectual property rights or might use our intellectual property improperly or in a way that jeopardizes our intellectual property or exposes us to potential liability; • collaboration activities might result in the collaborator having intellectual property covering our activities or product candidates, which could limit our rights or ability to research, develop and / or commercialize our product candidates; • collaborators might not be in compliance with laws applicable to their activities under the collaboration, which could impact the collaboration and us; • disputes might arise between a collaborator and us that could cause a delay or termination of the collaboration or result in costly litigation that diverts management attention and resources; and • collaborations might be terminated, which could result in a need for additional capital to pursue further research, development

and / or commercialization of our product candidates. In addition, funding provided by a collaborator might not be sufficient to advance product candidates under the collaboration. If a collaborator terminates a collaboration or a program under a collaboration, including by failing to exercise a license or other option under the collaboration, whether because we fail to meet a milestone or otherwise, any potential revenue from the collaboration would be significantly reduced or eliminated. In addition, we will likely need to either secure other funding to advance research, development and / or commercialization of the relevant product candidate or abandon that program, the development of the relevant product candidate could be significantly delayed, and our cash expenditures could increase significantly if we are to continue research, development and / or commercialization of the relevant product candidates. Any one or more of these risks, if realized, could reduce or eliminate future revenue from product candidates under our collaborations, and could have a material adverse effect on our business, financial condition, results of operations and / or growth prospects. We have established collaborations with Mabwell and NIH and may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans. Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies, such as our collaborations with Mabwell and NIH, for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s own evaluation of a potential collaboration. Such factors a potential collaborator will use to evaluate a collaboration may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us. We are also restricted by Roche' s right of first negotiation under our current license agreement with them and may in the future be restricted under other license or collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. In addition, any future collaborations that we enter into may not be successful. 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 regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision- making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation. We contract with third parties for the manufacture of our product candidates for preclinical development and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts. We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities. Although we believe we have obtained sufficient material to produce bitopertin tablets to complete our ongoing Phase 2 clinical ~~trials~~ **trial** , **and** DISC- 0974 vials to complete our ongoing Phase 1b / 2 clinical trials, ~~and vials to complete our Phase 1 trial of DISC- 3405,~~ we cannot be sure we have correctly estimated our drug product and API requirements or that such drug product or API will not expire before we want to use it. ~~While we have identified a contract development and manufacturing organization, or CDMO, to produce our own GMP material, we are in the early stages of manufacturing such material.~~ We rely, and expect to continue to rely, on third parties **such as contract development and manufacturing organizations, or CDMOs,** for the manufacture of our product candidates for preclinical development and clinical testing ~~, including Mabwell for the supply of vials to complete our Phase 1 trial of DISC- 3405~~ . We also expect to rely on third parties for the commercial manufacture of our products if any of our product candidates receive regulatory approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. The facilities used by our CDMOs to manufacture our product candidates must be inspected by the FDA pursuant to pre- approval inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and will be completely dependent on, our CDMOs for compliance with cGMPs in

connection with the manufacture of our product candidates. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to pass regulatory inspections and / or maintain regulatory compliance ~~for our manufacturing facilities~~. In addition, we have no control over the ability of our CDMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it finds deficiencies or withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. If any CDMO with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CDMO, which we may not be able to do on reasonable terms, if at all. In such a scenario, our clinical trials supply could be delayed significantly as we ~~established~~ -- **establish** alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back- up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Further, our failure, or the failure of our CDMOs, to comply with applicable regulations could result in sanctions ~~being imposed on it~~, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates. We may be unable to establish any additional agreements with CDMOs or do so on acceptable terms. Reliance on CDMOs entails additional risks, including: • reliance on the third party for regulatory compliance and quality assurance; • the possible breach of the manufacturing agreement by the third party; • the possible misappropriation of our proprietary information, including our trade secrets and know- how; and • the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. Our product candidates and any products that we may develop may compete with other product candidates and approved products for access to manufacturing facilities. There are a limited number of CDMOs that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval. If our current CDMOs cannot perform as agreed, we may be required to replace such CDMOs. In addition, there has been increased governmental focus in the U. S. on contracting with Chinese companies for the development or manufacturing of pharmaceutical products. **For example, there** ~~Efforts to discourage such contracting~~ have **been Congressional** ~~included U. S.~~ legislative proposals **, such as the bill titled the BIOSECURE Act that was previously considered (** and ~~a recent call~~ **not enacted) in Congress, which would have, among other things, prohibited U. S. federal funding in connection with biotechnology equipment or services produced or provided by certain named Chinese " biotechnology companies of concern " (which includes WuXi AppTech (Hong Kong) Limited and its affiliates, or WuXi) and loans and grants to, and federal contracts with any entity that uses biotechnology equipment or services** from **one of these entities. The legislation would also have given the federal government the authority to name additional " biotechnology companies of concern " that are engaged in research activities with the Chinese government and that pose a risk of U. S. national security. We currently rely on** certain **foreign or foreign- owned third- party vendors, including WuXi and its affiliates, to manufacture certain materials used in clinical trials of our product candidates or to provide services in connection with certain clinical trials or certain discovery activities. Our engagement with these foreign and foreign- owned vendors may be subject to new** U. S. ~~legislators~~ **legislation similar** to ~~add WuXi AppTec Co., Ltd., WuXi' s parent company, and~~ the **proposed BIOSECURE Act** ~~affiliated WuXi Biologics to the Department of Defense' s Chinese Military Companies List (1260H list)~~, **investigations** ~~the Department of Commerce' s Bureau of Industry and Security Entity List~~, ~~and the Department of Treasury' s Non- SDN Chinese Military- Industrial Complex Companies List. While the Biden administration has yet to take action~~ **sanctions , trade restrictions and other foreign regulatory requirements, which could cause us to need to identify alternate service providers, increase the cost or reduce the supply of materials available to us, delay the procurement or supply of these materials, delay or impact clinical trials, or have an adverse effect** on ~~this letter, adding either or~~ **our** ~~both previously mentioned WuXi entities~~ **ability to secure significant commitments from governments to purchase our potential therapies, any of which could adversely affect our financial condition and business prospects. We continue to assess the legislation as it develops to determine the effect, if any,** on ~~any or~~ **our contractual relationships** ~~all of the aforementioned lists or other geopolitical tensions with China could lead to material supply chain disruptions or delays for our biologic drug candidates manufactured by WuXi Biologics. We may incur added costs and delays in identifying and qualifying any replacement CDMOs~~ . Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis. The third parties upon whom we rely for the supply of the active pharmaceutical ingredients used in our product candidates are our sole sources of supply, and the loss of any of these suppliers could significantly harm our business. The active pharmaceutical ingredients, or API, used in certain of our product candidates are supplied to us from single-

source suppliers. Our ability to successfully develop our product candidates, and to ultimately supply our commercial products in quantities sufficient to meet the market demand, depends in part on our ability to obtain the API for these products in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. We do not currently have arrangements in place for a redundant or second- source supply of any such API in the event any of our current suppliers of such API cease their operations for any reason. We are also unable to predict how changing global economic conditions or potential global health concerns or crises will affect our third- party suppliers and manufacturers **. Regional issues may in some cases accentuate these risks. For example, the pharmaceutical industry generally, and in some instances we or other third parties on which we rely, depend on China- based suppliers or service providers for certain raw materials, products and services, or other activities. Our ability or the ability of our collaborators or such other third parties to continue to engage these China- based suppliers or service providers for certain preclinical research programs and clinical development programs could be restricted due to geopolitical developments between the United States and China, including as a result of the escalation of tariffs or other trade restrictions or if the previously proposed federal legislation known as the BIOSECURE Act or a similar law were to be enacted** . Any negative impact of such matters on our third- party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition. For all of our product candidates, we intend to identify and qualify additional manufacturers to provide such API prior to submission of an NDA to the FDA and / or an MAA to the EMA. We are not certain, however, that our single- source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess our ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers. Establishing additional or replacement suppliers for the API used in our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory inspection or approval, which could result in further delay. While we seek to maintain adequate inventory of the API used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects. The manufacture of biologics is complex and our third- party manufacturers may encounter difficulties in production. If any of our third- party manufacturers encounter such difficulties, our ability to provide supply of product candidates for clinical trials or products for patients, if approved, could be delayed or prevented. DISC- 0974, DISC- 0998, and DISC- 3405 are monoclonal antibodies. Manufacturing biologics, like monoclonal antibodies, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain regulatory approval for any of our current product candidates or any future product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. Risks Related to Our Intellectual Property If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired, and we may not be able to compete effectively in our market. Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the U. S. and other countries for our current or future product candidates, including our current lead product candidates, bitopertin, DISC- 0974 and DISC- 3405, and our other current or future programs, including DISC- 0998, as well as for their respective compositions, formulations, methods used to manufacture them and methods of treatment, in addition to successfully defending these patents against third- party challenges. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the U. S. and abroad related to our proprietary technology, inventions, and improvements that are important to the development and implementation of our business. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We also rely on trade secrets, know- how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. We have in- licensed, and may in the future in- license, a portion of our intellectual property, and, if we fail to comply with our obligations under these license arrangements, we could lose such

intellectual property rights or owe damages to the licensor of such intellectual property. In particular, we have exclusively licensed intellectual property rights from Roche to develop and commercialize bitopertin, including certain back- up compounds and derivatives, for all prophylactic and therapeutic uses. The Roche license covers know- how, and certain specified Roche patent rights, including a composition of matter patent for bitopertin that expires in 2025. We also have exclusively licensed intellectual property rights from AbbVie Deutschland GmbH & Co. KG, or AbbVie, to develop and commercialize DISC- 0974 and DISC- 0998. The AbbVie license covers know- how, and certain specified AbbVie patent rights, including composition of matter and methods of use patents and patent applications for DISC- 0974 and DISC- 0998. We also have exclusively licensed intellectual property rights from Mabwell to develop and commercialize antibody products containing Mabwell' s MWTX- 001, MWTX- 002, and MWTX- 003 antibodies. The Mabwell license covers know- how and certain specified Mabwell patent rights, including composition of matter and methods of use patents and patent applications for MWTX- 001, MWTX- 002 and MWTX- 003. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The degree of patent protection we require to successfully commercialize our current or future product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect bitopertin, DISC- 0974, DISC- 3405 or our other current or future product candidates. In addition, if the breadth or strength of protection provided by our patent applications or any patents we may own or in- license is threatened, we could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U. S. For example, in jurisdictions outside the U. S., a license may not be enforceable unless all the owners of the intellectual property agree or consent to the license. Accordingly, any actual or purported co- owner of our patent rights could seek monetary or equitable relief requiring us to pay it compensation for, or refrain from, exploiting these patents due to such co- ownership. Furthermore, patents have a limited lifespan. In the U. S., and most other jurisdictions in which we have undertaken patent filings, the natural expiration of a patent is generally twenty years after it is filed, assuming all maintenance fees are paid. Various extensions may be available, on a jurisdiction- by- jurisdiction basis; however, the life of a patent, and thus the protection it affords, is limited. Additionally, our product candidates may or may not be eligible for such extensions or we may not be able to obtain such protections due to procedural or other reasons. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, patents we may own or in- license may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing drugs similar or identical to our current or future product candidates, including generic versions of such drugs. Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents, with respect to either the same compounds, methods, formulations or other subject matter, in either case that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U. S. and other jurisdictions are typically not published until at least 18 months after the earliest priority date of the patent filing, or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in patents we may own or in- license patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty. In addition, the patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to certain pending patent applications covering our current or future product candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the relevant patent office (s) may be significantly narrowed by the time they issue, if they ever do. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Prosecution could require that claim scope narrow such that a clinical or product candidate or program is not adequately protected by the patent. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Even if we acquire patent protection that we expect should enable us to establish and / or maintain a competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U. S. and abroad. We may become involved in post- grant proceedings such as opposition, derivation, reexamination, inter partes review, post- grant review, invalidation, or interference proceedings challenging our patent rights or the patent rights of others from whom we may in the future obtain licenses to such rights, in the U. S. Patent and Trademark Office, or USPTO, the European Patent Office, or EPO, or in other countries. In addition, we may be subject to a third- party submission to the USPTO, the EPO, or elsewhere, that may reduce the scope or preclude the granting of claims from our pending patent applications. Competitors may allege that they invented the inventions claimed in our issued patents or patent applications prior to us, or may file patent applications before we do. Competitors may also claim that we are infringing their patents and that we therefore cannot practice our technology as claimed under our patents or patent applications. Competitors may also contest our patents by claiming to an administrative patent authority or judge that the invention was not patent-eligible, was not original, was not novel, was obvious, and / or lacked inventive step, and / or that the patent application filing

failed to meet relevant requirements relating to description, basis, enablement, clarity, and / or support; in litigation, a competitor could claim that our patents, if issued, are not valid or are unenforceable for a number of reasons. If a court or administrative patent authority agrees, we would lose our protection of those challenged patents. In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know- how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. An adverse determination in any such submission or proceeding 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 drugs, without payment to it, or could limit the duration of the patent protection covering our technology and current or future product candidates. Such challenges may also result in our inability to manufacture or commercialize our current or future product candidates without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if they are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent patents we may own or in- license by developing similar or alternative technologies or products in a non- infringing manner. For example, a third- party may develop a competitive product that provides benefits similar to one or more of our current or future product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our current or future product candidates could be negatively affected, which would harm our business. Furthermore, even if we are able to issue patents with claims of valuable scope in one or more jurisdictions, we may not be able to secure such claims in all relevant jurisdictions, or in a sufficient number to meaningfully reduce competition. Our competitors may be able to develop and commercialize their products, including products identical to ours, in any jurisdiction in which we are unable to obtain, maintain or enforce such patent claims. Furthermore, generic manufacturers may develop, seek approval for and launch generic versions of our products, and may challenge the scope, validity or enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or other proceedings. We also intend to rely on regulatory exclusivity for protection of our product candidates, if approved for commercial sale. Implementation and enforcement of regulatory exclusivity, which may consist of regulatory data protection and market protection, varies widely from country to country. Failure to qualify for regulatory exclusivity or failure to obtain or to maintain the extent or duration of such protections that we expect for our product candidates, if approved, could affect our decision on whether to market the products in a particular country or countries or could otherwise have an adverse impact on our revenue or results of operations. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, deadlines, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. We may miss a filing deadline for patent protection on these inventions. The USPTO and foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after issuance of any patent. In addition, periodic maintenance fees, renewal fees, annuity fees and / or various other government fees are required to be paid periodically. While an inadvertent lapse can, in some cases, be cured by payment of a late fee, or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition. If our trademarks and trade names for our products or company name are not adequately protected in one or more countries where we intend to market our products, we may delay the launch of product brand names, use different trademarks or tradenames in different countries, or face other potentially adverse consequences to building our product brand recognition. Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO or from comparable agencies in foreign jurisdictions objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and / or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. If we are unable to adequately protect and enforce our trade secrets, our business and competitive position would be harmed. In addition to the protection afforded by patents we may own or in- license, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know- how that may

not be patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know- how, information or technology that may not be covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information. Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets 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 intellectual property both in the U. S. and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party' s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be ineffective or breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may initiate, become a defendant in or otherwise become party to lawsuits to protect or enforce our intellectual property rights, which could be expensive, time- consuming, and unsuccessful. Competitors may infringe any patents we may own or in- license. In addition, any patents we may own or in- license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in- license is not valid or is unenforceable or that the other party' s use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U. S. C. § 271 (e) (1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or in- license do not cover the technology in question or that such third- party' s activities do not infringe our patent applications or any patents we may own or in- license. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in- license at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of its greater financial resources and more mature and developed intellectual property portfolios. 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. Post- grant proceedings provoked by third parties or brought by or before the USPTO or other patent granting authority may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may own or in- license. These proceedings are expensive and an unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to us from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO post- grant proceedings, we may become a party to patent opposition proceedings in the EPO, or similar proceedings in other foreign patent offices or courts where our patents may be challenged. The costs of these proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result in a post- grant challenge proceeding may result in the loss of

our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. Litigation or post- grant proceedings within patent offices may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U. S. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. We may not be able to detect infringement against any patents we may own or in- license. Even if we detect infringement by a third party of any patents we may own or in- license, we may choose not to pursue litigation against or settlement with the third party. If we later sue such third- party for patent infringement, the third- party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in- license against such third party. Intellectual property litigation and administrative patent office patent validity challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. 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 substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. As noted above, 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 compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our current or future product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects. We may be subject to damages or settlement costs resulting from claims that we or our employees have violated the intellectual property rights of third parties, or are in breach of our agreements. We may be accused of, allege or otherwise become party to lawsuits or disputes alleging wrongful disclosure of third- party confidential information by us or by another party, including current or former employees, contractors or consultants. In addition to diverting attention and resources to such disputes, such disputes could adversely impact our business reputation and / or protection of our proprietary technology. The intellectual property landscape relevant to our product candidates and programs is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including derivation, interference, reexamination, inter partes review and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our current or future licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and / or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. We cannot assure you that our current or future product candidates and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other valid intellectual property rights owned by third parties. For example, many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual' s former employer. We may also be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants and advisors, even those related to one or more of our current or future product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. While certain activities related to development and clinical testing of our current or future product candidates may be subject to safe harbor of patent infringement, such as under 35 U. S. C. § 271 (e) (1), upon receiving regulatory approval for such candidates we or any of our current or future licensors or strategic partners may immediately become party to, exposed to or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that such product candidates infringe, misappropriate or otherwise violate their intellectual property rights. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our current or future product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current or future product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs,

products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our current or future product candidates, technologies or methods. If a third party claims that we infringe, misappropriate or otherwise violate its intellectual property rights, we may face a number of issues, including, but not limited to: • infringement, misappropriation and other intellectual property claims which, regardless of merit, may be expensive and time- consuming to litigate and may divert our management' s attention from our core business and may impact our reputation; • substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates or violates the third party' s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner' s attorneys' fees; • a court prohibiting us from developing, manufacturing, marketing or selling our current product candidates, including bitopertin, DISC- 0974 and DISC- 3405, or future product candidates, or from using our proprietary technologies, unless the third- party licenses its product rights to us, which we are not required to do, on commercially reasonable terms or at all; • if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and / or grant cross- licenses to intellectual property rights for our products, or the license to us may be non- exclusive, which would permit third parties to use the same intellectual property to compete with us; • redesigning our current or future product candidates or processes so they do not infringe, misappropriate or violate third- party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; and • there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. 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 or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects. We may choose to challenge the patentability of claims in a third party' s U. S. patent by requesting that the USPTO review the patent claims in an ex- parte re- exam, inter partes review or post- grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party' s patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our current or future product candidates or proprietary technologies. Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the U. S. by law enjoy a presumption of validity that can be rebutted in U. S. courts only with evidence that is " clear and convincing, " a heightened standard of proof. There may be issued third- party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current or future product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the U. S. may be maintained in secrecy until the patents are issued, patent applications in the U. S. and many foreign jurisdictions are typically not published until 18 months after their earliest priority filing date, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our current or future product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over our patent applications or patents we may own or in- license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non- exclusive basis. There may be currently pending third- party patent applications which may later result in issued patents that our current or future product candidates may infringe. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our current or future product candidates or other technologies, could be found to be infringed by our current or future product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted or not infringed by our activities. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of our current or future product candidates, molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third- party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, or at all, our ability to commercialize our current or future product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our current or future product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay

royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our current or future product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our current or future product candidates, which could harm our business significantly. We may be unable to obtain patent or other intellectual property protection for our current or future product candidates or our future products, if any, in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection. We may not be able to pursue patent coverage of our current or future product candidates in all countries. Filing, prosecuting and defending patents on current or future product candidates in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the U. S. can be less extensive than those in the U. S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U. S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S., or from selling or importing products made using our inventions in and into the U. S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the U. S. These products may compete with our current or future product candidates and in jurisdictions where we do not have any issued patents, our patent applications or other intellectual property rights may not be effective or sufficient to prevent them from competing. Much of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines. 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, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products and / or methods of using biopharmaceutical products, which could make it difficult for us to stop the infringement of any patents we may own or in- license or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce any rights we may have in our patent applications or any patents we may own or in- license in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we may own or in- license at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents we may own or license that are relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. We may not obtain or grant licenses or sublicenses to intellectual property rights in all markets on equally or sufficiently favorable terms with third parties. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing of third- party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third- party intellectual property rights that we may consider attractive or necessary. More established companies may have a competitive advantage over us due to their size, capital 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 rights to us. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected current or future product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation. 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. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects. If we fail to comply with our obligations in any agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. We are party to license agreements with Roche, AbbVie and Mabwell and we may from time to time in the future be party to other license and collaboration agreements with third parties to advance our research or allow commercialization of current or future product candidates. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. See “ Business- Collaborations and License Agreement ” for more information regarding our license agreements with Roche, AbbVie and Mabwell. In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our current or future product candidates, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our current or future product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that is not subject to the licensing agreement; • our right to sublicense patent and other rights to third parties under collaborative development relationships; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our current or future product candidates, and what activities satisfy those diligence obligations; • the priority of invention of any patented technology; and • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners. In addition, the agreements under which we may license intellectual property or technology from third parties are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected current or future product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects. Any granted patents we may own or in- license covering our current or future product candidates or other valuable technology could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the U. S. or abroad, including the USPTO and the EPO. A patent asserted in a judicial court could be found invalid or unenforceable during the enforcement proceeding. Administrative or judicial proceedings challenging the validity of our patents or individual patent claims could take months or years to resolve. If we or our licensors or strategic partners initiate legal proceedings against a third party to enforce a patent covering one of our current or future product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and / or unenforceable. In patent litigation in the U. S., defendant counterclaims alleging invalidity and / or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, lack of written description, lack of novelty, obviousness, or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO that was material to patentability, or made a misleading statement, in the process of obtaining the patent during patent prosecution. Third parties may also raise similar claims before administrative bodies in the U. S. or abroad, even outside the context of litigation. Such mechanisms include re- examination, inter partes review, post grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patent applications or any patents we may own or in- license in such a way that they no longer cover our current or future product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, any rights we may have from our patent applications or any patents we may own or in- license, allow third parties to commercialize our current or future product candidates or other technologies and compete directly with us, without payment to us or result in our inability to manufacture or commercialize products without infringing third- party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post- grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our current or future licensors' priority of invention or other features of patentability with respect to our patent applications and any patents we may own or in- license. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our current or future product candidates and other technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our current or future licensing partners and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our current or future product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and current or future product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non- exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the current or future product candidates we may develop. The loss of exclusivity or the narrowing of our patent application claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects. Changes in patent law could

diminish the value of patents in general, thereby impairing our ability to protect our current or future product candidates. 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 involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the U. S. and other countries, including the Leahy- Smith America Invents Act, or Leahy- Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost- effective avenues for competitors to challenge the validity of patents. In addition, the Leahy- Smith Act has transformed the U. S. patent system into a " first inventor to file " system. The first- inventor- to- file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition. 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. Additionally, there have been recent proposals for additional changes to the patent laws of the U. S. and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U. S. Congress, the U. S. courts, the USPTO and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might subject us to infringement claims or adversely affect our ability to develop and market our current or future product candidates. We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending patent application in the U. S. and abroad that is relevant to or necessary for the commercialization of our current or future product candidates in any jurisdiction. For example, U. S. patent applications filed before November 29, 2000 and certain U. S. patent applications filed after that date that will not be filed outside the U. S. remain confidential until patents issue. As mentioned above, patent applications in the U. S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our current or future product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our current or future product candidates or the use of our current or future product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope and / or validity of a patent or a pending application may be incorrect, which may negatively impact our ability to market our current or future product candidates. We may incorrectly determine that our current or future product candidates are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U. S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our current or future product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our current or future product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our current or future product candidates that are held to be infringing. We might, if possible, also be forced to redesign current or future product candidates so that we no longer infringes the third- party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects. Intellectual property rights do not guarantee commercial success of current or future product candidates or other business activities. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights. The degree of future protection afforded by our intellectual property rights, whether owned or in- licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative: • patent applications that we own or may in- license may not lead to issued patents; • patents, should they issue, that we may own or in- license, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable; • others may be able to develop and / or practice technology, including compounds that are similar to the chemical compositions of our current or future product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in- license, should any patents issue; • third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection; • we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in- license; • we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering a particular invention; • others may independently develop similar or alternative technologies without infringing, misappropriating or

otherwise violating our intellectual property rights; • our competitors might conduct research and development activities in the U. S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not be able to obtain and / or maintain necessary licenses on reasonable terms or at all; • third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property; • we may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third-party may subsequently file a patent covering such trade secrets or know- how; • we may not be able to maintain the confidentiality of our trade secrets or other proprietary information; • we may not develop or in- license additional proprietary technologies that are patentable; and • the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects. Risks Related to Government Regulation Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants regulatory approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In short, the foreign regulatory approval process involves all of the risks associated with FDA approval. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we may intend to charge for our products will also be subject to approval. We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and / or receive applicable regulatory approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. We may seek priority review designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process. If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six- month review cycle or at all. We may seek orphan drug designation for certain of our product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity. We have received orphan drug designation from the FDA for bitopertin for the treatment of EPP and for DISC- 3405 for the treatment of PV. As part of our business strategy, we may seek orphan drug designation for certain of our product candidates and indications, as appropriate. 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 drug or biologic as an orphan drug if it is a product 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, or a patient population of 200, 000 or more in the United States where there is no reasonable expectation that the cost of developing the product will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. Similarly, in the European Union, the European Commission, upon the recommendation of the EMA' s Committee for Orphan Medicinal Products, grants orphan designation in respect of products that are intended for the diagnosis, prevention or treatment of life- threatening or chronically debilitating conditions affecting no more than 5 in 10, 000 persons in the European Union. Additionally, designation may be granted for products intended for the diagnosis, prevention, or treatment of a life- threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the product in the European Union would generate sufficient return to justify the necessary investment in developing the product. In each case, there must be no satisfactory method of diagnosis, prevention, or treatment of the applicable condition which is authorized for marketing in the European Union (or, if such a method exists, the applicable product would be of significant benefit to those affected by the condition). In the European Union, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers. The European Committee for Orphan Medical Products adopted a positive opinion on Orphan Designation for bitopertin for treatment of EPP. Generally, if a product with an orphan designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing

application for the same product and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in the European Union. The European Union market exclusivity period can be reduced to six years if, at the end of the fifth year, it is determined that a product no longer meets the criteria for orphan designation, including if the product is sufficiently profitable so that market exclusivity is no longer justified. Even if we obtain orphan drug exclusivity for one of our product candidates, that exclusivity may not effectively protect our product candidate from competition because different products can be approved for the same condition. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition or if another product with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a product nor gives the product any advantage in the regulatory review or approval process. While we may seek orphan drug designation for our product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations. The FDA may further reevaluate its regulations and policies under the Orphan Drug Act. We do not know if, when or how the FDA may change its orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. We ~~may seek~~ **have received** rare pediatric disease designation for bitopertin. However, a marketing application for bitopertin, if approved, may not meet the eligibility criteria for a rare pediatric disease priority review voucher. ~~We may seek~~ **In May 2024, we received** rare pediatric disease designation for bitopertin in patients with EPP and XLP. The FDA defines " rare pediatric disease " as a (i) serious or life- threatening disease in which the serious or life-threatening manifestations primarily affect ages from birth to 18 years, including age groups often called neonates, infants, children and adolescents; and (ii) a rare disease or condition within the meaning of the Orphan Drug Act. Designation of a product candidate as a product for a rare pediatric disease does not guarantee that a marketing application for such product candidate will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. ~~Under the Federal Food, Drug, and Cosmetic Act, we will need to request a rare pediatric disease priority review voucher in our original marketing application for our product candidates for which we have received rare pediatric disease designation.~~ The FDA may determine that a marketing application for bitopertin, if approved, does not meet the eligibility criteria for a priority review voucher. Under the current statutory sunset provisions ~~, after September 30, 2024~~ , the FDA may only award a priority review voucher for an approved rare pediatric disease product application if the sponsor has rare pediatric disease designation for the drug or biologic that is the subject of such application, and that designation was granted by ~~September 30~~ **December 20** , 2024. After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers. **As such, if we do not obtain approval of a marketing application for bitopertin in patients with EPP and XLP on or before September 30, 2026, we may not receive a priority review voucher.** However, it is possible **that** the **FDA' s** authority **to grant rare pediatric disease designation** ~~for~~ **or** ~~FDA to~~ award rare pediatric disease priority review vouchers will be further extended by Congress. ~~As such, if we do not obtain approval of a marketing application for bitopertin in patients with EPP and XLP on or before September 30, 2026, and if the priority review voucher program is not extended by Congressional action, we may not receive a priority review voucher.~~ A breakthrough therapy designation and fast track designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review or approval process, and each designation does not increase the likelihood that any of our product candidates will receive regulatory approval in the United States. We may seek a breakthrough therapy designation for certain of our product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates are designated as breakthrough therapies, the FDA may later withdraw the designation if it determines that such product candidates no longer meet the conditions for such designation. We were granted fast track designation by the FDA for DISC- 3405 for the treatment of PV in September 2023 and for DISC- 0974 for the treatment of anemia in non- dialysis dependent chronic kidney disease in February 2024, and we may seek fast track designation for certain of our product candidates. If a drug or biologic is intended for the treatment of a serious or life- threatening condition and the drug or biologic demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, the FDA may disagree and instead decide not to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation no longer meets the conditions for such designation. Fast track designation alone

does not guarantee qualification for the FDA' s priority review procedures. **We may seek approval from the FDA for bitopertin or any of our other current or future product candidates under the** Accelerated **Approval Program. If we are not able to use such program, we may be required to conduct additional clinical trials beyond those that are contemplated, which would increase the expense of obtaining, and delay the receipt of, necessary marketing** ~~approval~~ **approvals** ~~by~~ **, if we receive** ~~the~~ **them** ~~FDA~~ **at all. In addition** , even if ~~granted for our current or any other~~ -- **the** ~~future product candidates~~ **Accelerated Approval Program is available to us** , **it** may not lead to **expedited** ~~a faster development or regulatory review or~~ approval **of** ~~process and it does not increase the likelihood that~~ our product candidates **, or** ~~will receive regulatory~~ approval **at all** . We may seek accelerated approval of **bitopertin** ~~our~~ - **or any of our other** current or future product candidates ~~using the FDA' s accelerated approval pathway~~ . A product may be eligible for accelerated approval if it treats a serious or life- threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. It is possible that at the time of submission of a marketing application, the FDA may determine that our product candidate is not eligible for accelerated approval or that accelerated approval is not warranted. Moreover, FDA may revise how it implements accelerated approval, which could negatively affect the development of our current or future product candidates. As a condition of approval, the FDA generally requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well- controlled post- marketing clinical trials. These confirmatory trials must be completed with due diligence. Under FDORA, the FDA is permitted to require, ~~as appropriate,~~ that a post- approval confirmatory trial or trials be underway prior to approval or within a specified time period after the date accelerated approval is granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such trials, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct confirmatory studies in a timely manner, send the necessary updates to the FDA, or if such post- approval trials fail to verify the product' s predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post- approval confirmatory trial or submit timely reports to the agency on their progress. In addition, the FDA currently requires, unless **the sponsor is** otherwise informed by the agency, **submission of launch promotional materials during the** pre- approval **period** ~~of promotional materials for products being considered for accelerated approval~~ , which could adversely impact the timing of the commercial launch of the product. **If** ~~Even if~~ we ~~do receive~~ **are not able to obtain** accelerated approval **for a product candidate** , we **may be required to conduct additional clinical trials beyond those that are contemplated, which would increase the expense of obtaining, and delay the receipt of, full FDA approval, if received at all. In November 2024, we announced that, based on discussions with the FDA, reduction in protoporphyrin IX, or PPIX, may be sufficient to serve as a surrogate endpoint supportive of submitting an NDA for bitopertin in EPP and XLP under the FDA' s Accelerated Approval Program based on our existing data. In January 2025, we announced that we had aligned with the FDA on the design of our planned APOLLO post- marketing confirmatory trial and that we plan to initiate the trial in mid- 2025 and submit an NDA for accelerated approval of bitopertin in EPP and XLP in the second half of 2025. However, the FDA could change its position regarding the sufficiency of PPIX as a surrogate endpoint or the design of our APOLLO clinical trial. Further, even if the FDA continues to agree that reduction of PPIX may be sufficient to serve as a surrogate endpoint supportive of submitting an NDA for accelerated approval of bitopertin in EPP and XLP and remains aligned with the design of APOLLO as a post- marketing confirmatory trial, the FDA** may not **accept** ~~experience a faster development or for~~ ~~regulatory review~~ **filing any NDA we submit** ~~or~~ **for accelerated** approval ~~process~~ **for bitopertin** , ~~and~~ **may not grant this approval on a timely basis, or may not grant approval at all.** ~~receiving~~ **Receiving** accelerated approval does not provide assurance of ultimate full FDA **approval. Even if the Accelerated Approval Program does result in a faster approval process, there is no guarantee that we will be able to begin commercialization of our product at the time of such approval, that the APOLLO trial will confirm and verify clinical benefit, or that we will be otherwise able to maintain such** approval. If our drug product candidates or any of our future drug product candidates obtain regulatory approval, additional competitors could enter the market with generic versions of such products, which may result in a material decline in sales of our competing products. Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch- Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, or the FDCA, a company may file an abbreviated new drug application, or ANDA, seeking approval of a generic version of an approved innovator product. Under the Hatch- Waxman Amendments, a company may also submit an NDA under section 505 (b) (2) of the FDCA that references the FDA' s prior approval of the innovator product or preclinical studies and / or clinical trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. A 505 (b) (2) NDA product may be for a new or improved version of the original innovator product. The Hatch- Waxman Amendments also provide for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505 (b) (2) NDA. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication " Approved Drug Products with Therapeutic Equivalence Evaluations, " known as the Orange Book. If there are patents listed in the Orange Book for the applicable, approved innovator product, a generic or 505 (b) (2) applicant that seeks to market our product before expiration of the patents must include in their applications what is known as a " Paragraph IV " certification, challenging the validity or enforceability, or claiming non- infringement, of the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505 (b) (2) NDA is stayed for up to 30 months. Accordingly, if any of our product candidates that are

regulated as drugs are approved, competitors could file ANDAs for generic versions of these products or 505 (b) (2) NDAs that reference our products. If there are patents listed for such drug products in the Orange Book, those ANDAs and 505 (b) (2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents or the outcome of any such suit. We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or licenses, despite expending a significant amount of resources that could have been focused on other areas of our business. Moreover, if any of our owned or in- licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and our sales would likely decline rapidly and materially. If approved, our investigational products regulated as biologics may face competition from biosimilars or interchangeable products approved through an abbreviated regulatory pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA- licensed reference biologic product. Under the BPCIA, an application for a biosimilar or interchangeable product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar or interchangeable product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12- year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity, and potency of the other company' s product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products ~~for competing products~~, potentially creating the opportunity for ~~generic~~ **biosimilar** competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of ~~recent~~ litigation. Moreover, the extent to which a biosimilar or interchangeable product, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain regulatory approval for biosimilars or interchangeable products referencing our products, our products may become subject to competition from such biosimilars or interchangeable products, with the attendant competitive pressure and consequences. The FDA, the EMA and other regulatory authorities may implement additional regulations or restrictions on the development and commercialization of our product candidates, and such changes can be difficult to predict. The FDA, the EMA and regulatory authorities in other countries have each expressed interest in further regulating biotechnology products. Agencies at both the federal and state level in the United States, as well as the U. S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical trials of products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post- approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. If any of our product candidates are approved and we are found to have improperly promoted off- label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while the FDA permits the dissemination of truthful and non- misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product' s approved labeling. ~~If we are found to have promoted such off- label uses, we may become subject to significant liability.~~ The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. Inadequate funding for the **NIH, CMS,** FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, **including significant leadership, personnel, or policy changes,** could ~~hinder their ability to hire and retain key leadership and other personnel,~~ prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

Currently, federal agencies in the U. S. are operating under a continuing resolution that is set to expire on March 14, 2025. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U. S. market could be impacted. The ability of the FDA to review and approve new products **, NIH' s ability to conduct and partner with industry on important research, and CMS' s ability to operate efficiently** can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at **these agencies, including, for example, as a result of the freeze on federal funding announced in January 2025 and other restrictions, such as personnel reductions at agencies such as** the FDA **,** ~~and other agencies~~ may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies **or may slow or stall planned or ongoing research** , which would adversely affect our business. For example, over the last several years the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown **or a widespread freeze on federal funding** occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions **, NIH to conduct research or provide grants, or other agencies to slow their work** , which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Healthcare ~~legislative~~ reform measures may have a material adverse effect on our business and results of operations. The U. S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the U. S. and global healthcare systems that could prevent or delay regulatory approval of our current or future product candidates or any future product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell a product for which we obtain regulatory approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record- keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. In the U. S., there have been and continue to be, on- going legislative initiatives to contain healthcare costs. For example, ~~in March 2010,~~ the Patient Protection and Affordable Care Act, or the ACA, ~~was passed,~~ as amended by the Health Care and Education Reconciliation Act of 2010, ~~which~~ substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U. S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower- cost biosimilars, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70 % point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D, and provided incentives to programs that increase the federal government' s comparative effectiveness research. Since then, the ACA risk adjustment program payment parameters have been updated annually. Since the ACA' s enactment, there have been numerous judicial, administrative, executive and legislative challenges to certain aspects of the ACA and we expect that there will be additional challenges and amendments to the ACA in the future. On June 17, 2021, for example, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. In addition, ~~President Biden has issued~~ multiple executive orders **have been issued** that **seek** ~~have sought~~ to reduce prescription drug costs. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the ~~Biden~~ **current** administration may reverse or otherwise change these measures, both the ~~Biden~~ **current** administration and Congress have indicated that they will continue to seek new ~~legislative~~ measures to control drug costs. It is unclear how ~~other~~ healthcare reform measures ~~of the Biden administrations~~ or other efforts, if any, to challenge repeal or replace the ACA, will impact our business. In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted: • The U. S. Budget Control Act of 2011, for example, included aggregate reductions of Medicare payments to providers of 2 % per fiscal year that will remain in effect through ~~2031~~ **2032** . ~~• The U. S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. • The Right to Try Act (2018) provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act. • CMS published a final rule that allows Medicare Advantage Plans the option of using step therapy for Part B drugs, effective January 1, 2020. • The U. S. American Rescue Plan Act of 2021, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024~~ . Due to the Statutory Pay- As- You- Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. **• The U. S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. • The U. S. American Rescue Plan Act of 2021, which eliminates the statutory Medicaid drug rebate cap, previously set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024.** There has been increasing legislative and

enforcement interest in the U. S. with respect to specialty drug pricing practices. Specifically, there have been several recent U. S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. ~~In addition, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.~~ The **Inflation Reduction Act of 2022, or the** IRA **,** includes several provisions that may impact our business, depending on how various aspects of the IRA are implemented. Provisions that may impact our business include a $ 2, 000 out- of- pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on most drugs in Medicare Part D, permitting the U. S. government to negotiate Medicare Part B and Part D pricing for certain high- cost drugs and biologics without generic or biosimilar competition, requiring companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of ~~which~~ **the IRA** is currently subject to ongoing litigation challenging the constitutionality of the IRA' s Medicare drug price negotiation **program. CMS has announced the results of the first round of negotiated prices between CMS and participating drug manufacturers for the ten selected drugs under the IRA' s Medicare drug price negotiation program. These prices go into effect in 2026. CMS has also announced the next 15 drugs selected for the IRA' s Medicare drug price negotiation program. It is unclear whether ongoing litigation will be successful in challenging the constitutionality of the IRA' s Medicare drug price negotiation program and, if so, may provide a mechanism to block the implementation of the** program. The effects of the IRA on our business and the healthcare industry in general is not yet known. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, or the frequency with which any such product candidate is prescribed or used, which could result in reduced demand for our current or future product candidates or additional pricing pressures. In particular any policy changes through CMS as well as local state Medicaid programs could have a significant impact on our business. Our revenue prospects could be affected by changes in healthcare spending and policy in the U. S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: • the demand for our current or future product candidates, if we obtain regulatory approval; • our ability to set a price that we believe is fair for our products; • our ability to obtain coverage and reimbursement approval for a product; • our ability to generate revenue and achieve or maintain profitability; • the level of taxes that we are required to pay; and • the availability of capital. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. Our relationships with customers, healthcare providers, physicians and third- party payors will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished future profits and earnings. Although we do not currently have any products on the market, once we begin commercializing our product candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third- party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our future arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain regulatory approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following: • the U. S. federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a

violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment of up to ten years, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. The HHS, Office of Inspector General, or OIG, heavily scrutinizes relationships between pharmaceutical companies and persons in a position to generate referrals for or the purchase of their products, such as physicians, other healthcare providers, and pharmacy benefit managers, among others. However, there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; • the federal civil and criminal false claims and civil monetary penalties laws, including the federal False Claims Act, or FCA, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to " cause " the submission of false or fraudulent claims. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti- Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act. The federal False Claims Act also permits a private individual acting as a " whistleblower " to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery; • the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program (e. g. public or private), or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the federal physician payment transparency requirements, sometimes referred to as the " Sunshine Act " under the ACA, which require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program to report to HHS information related to transfers of value made to physicians, nurse practitioners, certified nurse anesthetists, physician assistants, clinical nurse specialists, and certified nurse midwives as well as teaching hospitals. Manufacturers are also required to disclose ownership and investment interests held by physicians and their immediate family members; • federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and • federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and / or discounts on approved products. We are also subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U. S. states have adopted laws similar to the federal Anti- Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and / or 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 and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. 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. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. In the U. S., to help patients afford our approved product, we may utilize programs to assist them, including patient assistance programs and co- pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, at least one insurer has directed its network pharmacies to no longer accept co- pay coupons for certain specialty drugs the insurer identified. Our co- pay coupon programs could become the target of similar insurer actions. In addition, in November 2013, the CMS issued guidance to the issuers of qualified health plans sold through the ACA' s marketplaces encouraging such plans to reject patient cost- sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. The CMS subsequently issued a rule requiring individual market qualified health plans to accept third- party premium and cost- sharing payments from certain government- related entities. In September 2014, the OIG of the HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti- kickback statute and / or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co- pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co- pay coupons. It is possible that changes in insurer policies regarding co- pay coupons and / or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition. Third party patient assistance programs that receive

financial support from companies have become the subject of enhanced government and regulatory scrutiny. The OIG has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co- pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first- come basis according to consistent financial criteria and do not link aid to use of a donor' s product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, co- pay, and co- insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses and reduce the availability of foundation support for our patients who need assistance. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the exclusion from participation in federal and state government funded healthcare programs, such as Medicare and Medicaid, reputational harm, and the curtailment or restructuring of our operations. It may also subject us to additional reporting obligations and oversight, if we become subject to a corporate integrity agreement, deferred prosecution agreement, or other agreement to resolve allegations of non- compliance with these laws. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to similar criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations. Compliance with U. S. and 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 expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. 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. We possess and process sensitive information, including patient health information. In the U. S., there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including health information privacy laws, security breach notification laws and consumer protection laws. These federal and state laws, in many cases, are not preempted by HIPAA and may be subject to varying interpretations by the courts and government agencies. These varying interpretations can create complex compliance issues for us and our partners and potentially expose us to additional expense, adverse publicity and liability, any of which could adversely affect our business. There is ongoing concern from privacy advocates, regulators and others regarding data privacy and security issues, and the number of jurisdictions with data privacy and security laws has been increasing. Also, there are ongoing public policy discussions regarding whether the standards for de- identification, anonymization or pseudonymization of health information are sufficient, and the risk of re- identification sufficiently small, to adequately protect patient privacy. We expect that there will continue to be new proposed and amended laws, regulations and industry standards concerning privacy, data protection and information security in the United States. For example, California

enacted the California Consumer Privacy Act, or CCPA, **a comprehensive privacy** ~~which took effect on January 1, 2020, and became enforceable by the California Attorney General on July 1, 2020. This~~ law **that** broadly defines personal information, gives California residents expanded rights to access and delete their personal information, and places stringent privacy and security obligations on businesses covered by the law, including obligations to provide detailed disclosures to California consumers about their data collection, use and sharing practices, and to provide such consumers with ways to opt out of certain sales or transfers of personal information. It also provides for civil penalties for violations, and allows for a private right of action for data breaches that is expected to increase data breach litigation. In addition, the **CCPA was amended by the** California Privacy Rights Act, or CPRA, which **as of** ~~became effective on~~ January 1, 2023, significantly modified the CCPA by expanding consumer rights with respect to certain sensitive information, and creating a new state agency that is vested with authority to implement and enforce the CCPA. Comprehensive laws similar to the CCPA have been passed in numerous other states outside of California. These laws are substantially similar in scope and contain many of the same requirements and exceptions as the CCPA, including a general exemption for clinical trial data and limited obligations for entities regulated by HIPAA. However, we cannot yet determine the full impact these laws or other such future laws, regulations and standards may have on our current or future business. Any of these laws may broaden their scope in the future, and similar laws have been proposed on both a federal level and in more than half of the states in the U. S. In addition, a number of other states have proposed new privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. Furthermore, in addition to comprehensive privacy laws, certain states have enacted laws to focus on particular more limited privacy laws. For example, the state of Washington has passed a law to protect medical and health information not subject to HIPAA. This law has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and / or passed legislation that regulates the privacy and / or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric information. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there **have been proposals for** ~~is discussion in the U. S. Congress of~~ a new comprehensive federal data privacy law to which we may likely become subject, if enacted. The collection, use, storage, disclosure, transfer or other processing of personal data regarding individuals in the EEA and UK, including personal health data, is subject to the EU General Data Protection Regulation 2016 / 679, or EU GDPR, with respect to individuals in the EEA and the UK General Data Protection Regulation (following the incorporation of the EU GDPR into UK law), or UK GDPR, with respect to individuals in the UK, and together with the EU GDPR, GDPR. The GDPR is wide- ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to having a legal basis **or condition** for processing personal data, stricter requirements relating to processing sensitive data (such as health data), where required by GDPR 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, requiring data protection impact assessments for high risk processing and taking certain measures when engaging third- party processors. The GDPR permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to € 20 million (**£** 17. 5 million for the UK) or 4 % of annual global revenues, whichever is greater. The GDPR 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. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is a rigorous and time- intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. The GDPR provides that EEA Member States may make their own further laws and regulations in relation to the processing of genetic, biometric or health data, which could result in differences between Member States, limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA and UK not deemed adequate for the transfer of such personal data by competent data protection authorities, or third countries, including the United States in certain circumstances unless a derogation exists or we may need to incorporate a GDPR transfer mechanism (such as the European Commission approved standard contractual clauses, or SCCs or the UK International Data Transfer Addendum, or IDTA) into our agreements with third parties to govern such transfers of personal data and carry out transfer impact assessments. Further, the European Union and United States have adopted its adequacy decision for the EU- U. S. Data Privacy Framework, or the Framework, which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the European Union and the United States is comparable to that offered in the European Union. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework could be challenged like its predecessor frameworks. The international transfer obligations under the EEA and UK data protection regimes will require effort and cost and may result in us needing to make strategic considerations around where EEA / UK personal data is located and which service providers we

can utilize for the processing of EEA / UK personal data. Although the UK is regarded as a third country under the EU GDPR, the European Commission has issued an " Adequacy Decision " recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data subject to the EU GDPR to the UK remain unrestricted. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The UK Government ~~has also now~~ introduced ~~a~~ **the** Data Protection and Digital Information Bill, **which failed in** ~~or the UK Bill, into~~ the UK legislative process ~~with the intention~~ **. A new Data (Use and Access) Bill,** ~~for~~ **or** ~~this bill to reform~~ the UK ~~' s data protection regime following Brexit~~ **Bill, has been introduced into parliament** . If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EU data protection regime and threaten the UK Adequacy Decision from the EU Commission. This may lead to additional compliance costs and could increase our overall risk **. In the EEA, the NIS 2 Directive, or NIS 2, is replacing the cybersecurity legal framework under the current NIS framework, aiming to ensure a high level of cybersecurity in the region. NIS 2 expands on the scope of the current NIS framework, extending to additional sectors and expanding the list of in- scope healthcare organisations providing services in the EEA, including to certain providers engaged in research and development of medicinal products. To the extent applicable, the new regime imposes direct obligations on management regarding compliance with NIS 2, requiring covered organisations to put in place certain cyber risk management measures, and strengthens incident reporting requirements and provides supervisory authorities with greater oversight. The majority of these obligations will not come into force until national legislation implementing NIS 2 becomes effective in the relevant EU Member State. EU Member States had until October 17, 2024 to transpose NIS 2 into national legislation, although many countries have still not completed this process. As such, the cybersecurity regulatory landscape in the EU is currently fragmented and uncertain. To the extent we become subject to NIS 2, we may need to increase investment in our cybersecurity compliance programs. Under NIS 2, companies may be subject to administrative fines of up to the higher amount of € 10 million or 2 % of worldwide annual revenue** . All of these evolving compliance and operational requirements impose potentially significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management' s time and / or divert resources from other initiatives and projects. If we or third- party CDMOs, CROs or other contractors or consultants fail to comply with U. S. and international data protection laws and regulations, it could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and / or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business, financial condition, results of operations and prospects. The use of new and evolving technologies, such as artificial intelligence, in our business may result in spending material resources and presents risks and challenges that can impact our business including by posing security and other risks to our confidential and / or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability. We may use and integrate artificial intelligence **, or AI,** into our business processes, and this innovation presents risks and challenges that could affect its adoption, and therefore our business. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. The use of certain **AI** ~~artificial intelligence~~ technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. **To the extent we develop our own AI systems, then the risk of intellectual property infringement could arise from third party data sources being used to train our AI models, and from the output of AI systems reproducing or incorporating third party intellectual property rights, in each case without the right to do so. Further, a risk of our proprietary intellectual property rights being compromised through the use of AI could arise through third party vendors using our data to train their models and / or to generate output for other users of their systems. If our third party vendors use our data (which includes personal data) to train their AI models and / or to generate output for other users of their systems, this could also give rise to regulatory risks.** Additionally, we expect to see increasing government and supranational regulation related to **AI** ~~artificial intelligence~~ use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the European Union' s Artificial Intelligence Act, or the AI Act, the world' s first comprehensive AI law, ~~is anticipated to enter~~ **entered** into force in ~~Spring~~ **August** 2024 and, with some exceptions, ~~become~~ **becomes** effective ~~24 months thereafter~~ **in August 2025** . This legislation imposes significant obligations on providers and deployers of high risk **AI** ~~artificial intelligence~~ systems, and encourages providers and deployers of **AI** ~~artificial intelligence~~ systems to account for European Union ethical principles in their development and use of these systems. If we develop or use AI systems that are governed by the AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. The rapid evolution of **AI** ~~artificial intelligence~~ will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that **AI** ~~artificial intelligence~~ is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate **AI** ~~artificial intelligence~~ tools into their offerings, and the providers of these **AI** ~~artificial intelligence~~ tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of **AI** ~~artificial intelligence~~ , to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects

could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business. Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs. If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U. S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Compliance with the FCPA 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. 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, it will require us 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. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. Risks Relating to Employee Matters and Managing Growth Our future success depends on our ability to retain key executives and experienced scientists and to attract, retain, and motivate qualified personnel. We are highly dependent on many of our key employees and members of our executive management team as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment letter agreements with certain of our executive officers, each of them may terminate their employment with us at any time. We do not maintain " key person " insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees, including temporary loss due to illness, could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel. In particular, we have experienced a very competitive hiring environment in the greater Boston area of Massachusetts, where we are headquartered. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high- quality candidates than what we have to offer. If we are unable to continue to attract and retain high- quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited. We may be unable to adequately protect our information systems and infrastructure from cyberattacks or security compromises, **cybersecurity** incidents or **data** breaches, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure. We rely on information technology systems and infrastructure that we or our third- party providers operate to process, transmit and store electronic information in our day- to- day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data and other confidential and / or proprietary data, such as names, mailing addresses, email addresses, phone numbers and clinical trial information. A successful cyberattack could result in the theft, destruction or misuse of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks generally are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, **insiders such as** employees, contractors or other third- parties and industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, **ransomware,** denial- of- service, social engineering fraud **(including phishing attacks)** or other means to threaten or compromise the security, confidentiality, integrity and availability of systems and information. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of protected information or confidential business

information, including personal data, financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. **Like other companies in our industry, we, and our third party vendors, have experienced, and will continue to experience, cybersecurity threats and incidents relating to our information technology systems and infrastructure.** Although we devote resources designed to protect our information systems and infrastructure, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent or adequately address information security compromises, incidents or breaches that would result in business, legal, financial or reputational harm to it, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate ~~security~~ **cybersecurity incidents, data** breaches, compromises or **other** ~~incidents or~~ improper access to, use of, or disclosure of protected information, including our clinical data or patients' personal data could **require us to notify impacted stakeholders (including affected individuals, regulators and investors) and** result in significant liability through litigation and regulatory investigations and enforcement actions, including under state (e. g., state breach notification and consumer protection laws), federal (e. g., HIPAA, as amended by **the Health Information Technology for Economic and Clinical Health Act of 2009 ("** HITECH **")**), and international law (e. g., the GDPR), and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business. We rely on our third- party providers to implement effective security measures and identify and correct for any such failures, deficiencies, vulnerabilities, compromises, **cybersecurity** incidents or **data** breaches. We also rely on our employees and consultants to safeguard their security credentials and follow our policies and procedures regarding use and access of computers and other devices that may contain protected information and our sensitive information. If we or our third- party providers fail to maintain or protect our information technology systems, infrastructure and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems and infrastructure, we or our third- party providers could have difficulty preventing, detecting and controlling such cyber- attacks, and any such attacks could result in the losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenue or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or adequately mitigate ~~security~~ **cybersecurity incidents, data** breaches, compromises or **other** ~~incidents or~~ improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or adequately mitigate the impact of such ~~security~~ **cybersecurity incidents, compromises** or data ~~privacy incidents, compromises or~~ breaches, we could be exposed to litigation and governmental investigations, inquiries, orders, penalties or fines, which could lead to a potential disruption to our business and financial penalties or losses. By way of example, the CCPA, which was modified by the CPRA, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties of up to $ 7, 500 per violation, as well as a private right of action for data breaches that has, and is expected to continue to, increase the volume of data breach related litigation filed in California. **Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Further, although we maintain cyber liability insurance, this insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or data breach.** We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As of ~~February 29~~ **December 31**, 2024, we had ~~74~~ **84** full- time employees and no part- time employees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly as we ~~function~~ **mature** as a public company and in the areas of product development, regulatory affairs and, ~~if any~~ **in anticipation** of **the potential** ~~our product candidates receives~~ regulatory approval **of bitopertin**, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. General Risk Factors Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non- performance by financial institutions or transactional counterparties, could adversely affect the Company' s current and projected business operations and its financial condition and results of operations. Events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each placed into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB (such as our Company) would have access to all of their money after only one business day

of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. Subsequent to these events, additional financial institutions have experienced similar failures and have been placed into receivership. It is possible that other banks will face similar difficulty in the future. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which the Company has credit agreements or arrangements directly, **such as Hercules Capital,** or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which the Company has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. Changes in tax law may adversely affect us or our investors. The rules dealing with U. S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U. S. will be capitalized and amortized, which may have an adverse effect on our cash flow. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law. Prospective investors should consult their tax advisors regarding the potential consequences of changes in tax law on our business and on the ownership and disposition of our common stock. Our future taxable income may be subject to certain limitations. As of December 31, ~~2023~~ **2024** , we had federal and state net operating loss carryforwards of $ ~~88~~ **117** . ~~1~~ **9** million and $ ~~91~~ **133** . ~~7~~ **8** million, respectively. Substantially all of the federal NOLs are not subject to expiration and the state NOLs begin to expire in 2037. As of December 31, ~~2023~~ **2024** , we also had federal and state research and development tax credit carryforwards of $ ~~5~~ **19. 0 million and $ 2** . 8 million ~~and $ 1. 8 million~~ , respectively, which begin to expire in ~~2032~~ **2034** . These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under current law, unused U. S. federal and certain state net operating losses generated for tax years beginning after December 31, 2017 are not subject to expiration and may be carried forward indefinitely. Such U. S. federal net operating losses generally may not be carried back to prior taxable years, except that, net operating losses generated in 2019, 2020 and 2021 may be carried back to each of the five tax years preceding the tax years of such losses. For taxable years beginning after December 31, 2020, the deductibility of U. S. federal net operating losses generated for tax years beginning after December 31, 2017 is limited to 80 % of our taxable income in any future taxable year. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an " ownership change " is subject to limitations on its ability to utilize its pre- change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs when one or more stockholders or groups of stockholders who each owns at least 5 % of a corporation' s stock increase their aggregate stock ownership by more than 50 percentage points over their lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change after the merger, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. We are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations. Among other matters, U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We also expect our non- U. S. activities to increase in time. We currently engage, and expect to continue to engage, third parties for clinical trials and / or to obtain necessary permits, licenses,

patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, in 2008, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets and the COVID- 19 pandemic has caused significant volatility and uncertainty in U. S. and international markets. See " Risks Related to the Discovery and Development of Our Product Candidates- A pandemic, epidemic, or outbreak of an infectious or highly contagious disease may materially and adversely affect our business and financial results and could cause a disruption to the development of our product candidates. " Interest rates in the U. S. have recently increased to levels not seen in decades. In addition, the impact of geopolitical tension, such as a deterioration in the bilateral relationship between the United States and China or an escalation in conflict between Russia and Ukraine and between Israel and Hamas, including any resulting sanctions, export controls or other restrictive actions, also could lead to disruption, instability and volatility in the global markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our products. 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. Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements or insider trading. We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, 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 commission, customer incentive programs and other business arrangements. Other activities subject to these laws include the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourself or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. The market price of our common stock is expected to be volatile. The market price of our common stock following the merger could be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include: • results of clinical trials and preclinical studies of our product candidates, or those of our competitors or our existing or future collaborators; • failure to meet or exceed financial and development projections we may provide to the public; • failure to meet or exceed the financial and development projections of the investment community; • if we do not achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts; • announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors; • actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms; • disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies; • additions or departures of key personnel; • significant lawsuits, including patent or stockholder litigation; • if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock; • changes in the market valuations of similar companies; • general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors; • sales of securities by us or our securityholders in the future; • if we fail to raise an adequate amount of capital to fund our operations and continued development of our product candidates; • trading volume of our common stock; • announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments; • adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets; • the introduction of technological innovations or new therapies that compete with our products and services; and • period- to- period fluctuations in our financial results. Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company' s securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our

strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. We **have incurred and** will **continue to** incur ~~additional~~ **increased** costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies. We will **continue to** incur significant legal, accounting and other expenses as a public company that we did not incur as a private company, including costs associated with public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act. **The Sarbanes- Oxley Act of 2002, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices.** Our management ~~team consists of our executive officers prior to the merger, some of whom have not previously managed and operated a public company. These executive officers~~ and other personnel **devote and** will need to **continue to** devote **a** substantial **amount of** time to **these** ~~gaining expertise related to public company reporting requirements and~~ compliance ~~with applicable laws~~ **initiatives. Moreover, these rules** and regulations **have increased and will continue** to ~~ensure that we comply with all of these requirements~~ **increase our legal and financial compliance costs and will make some activities more time- consuming and costly** . Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms. ~~Once~~ **If** we ~~are no longer~~ **fail to maintain** an **effective system** ~~emerging growth company, a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results. We are subject to the reporting requirements~~ of ~~the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. However, as an emerging growth company we may take advantage of exemptions from various requirements such as an exemption from the requirement to have our independent auditors attest to our~~ internal control over financial reporting ~~under~~ **, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. As described further below, we have identified a material weakness in our internal control over financial reporting. Any testing by us conducted in connection with** Section 404 **, or** ~~of the Sarbanes- Oxley Act of 2002 as well as an~~ **any** ~~exemption~~ **testing by our independent registered public accounting** ~~from~~ **firm** ~~the " say on pay " voting requirements pursuant to the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010. After we no longer qualify as an emerging growth company~~ , ~~we~~ may ~~still qualify as a " smaller~~ **reveal additional deficiencies in our internal control over financial** reporting **that are deemed** ~~company " which may allow us~~ to **be material weaknesses or that may** ~~take advantage of some of the same exemptions from disclosure requirements including not being required~~ **require prospective or retroactive changes** to ~~comply with~~ **our financial statements or identify** ~~the~~ **other** ~~auditor~~ **areas for further** ~~attestation~~ **attention** ~~requirements of~~ **or improvement. Pursuant to** Section 404 **, we are required to furnish a** ~~of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports~~ **report by our management on our internal control over financial** ~~and proxy statements. Even after we no longer qualify as an emerging growth company, we expect to still qualify as a " smaller~~ reporting **. To continue** ~~company, " as such term is defined in Rule 12b- 2 under the Exchange Act, in at least the near term, which will allow us~~ to **achieve and maintain compliance** ~~take advantage of many of the same exemptions from disclosure requirements, including not being required to comply~~ with ~~the auditor attestation requirements of~~ Section 404 ~~of the Sarbanes- Oxley Act~~ **, we engage in a process to document** and ~~reduced disclosure obligations~~ **evaluate our internal control over financial reporting, which is both costly and challenging. In this** ~~regarding~~ **regard, we need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, from time to time we may not be able to conclude that our internal control over financial reporting is** ~~executive~~ **effective** ~~compensation~~ **as required by Section 404, as is the case** in this Annual Report on Form 10- K ~~and in our periodic reports and proxy statements. Once we are no longer an emerging growth company~~ , **due to** ~~a smaller reporting company or otherwise qualify for these~~ **the material weakness** ~~exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies~~ **identified** ~~deficiencies~~ **and described below. Additionally, the material weakness** in our internal control over financial reporting **has resulted in our management being unable to conclude, and any additional material weakness in our internal control over financial reporting may in the future result in our management being unable to conclude, that our disclosure controls and procedures were effective for the applicable period. In addition, as we no longer qualify as a non- accelerated filer or an emerging growth company, we are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to**

maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, and our independent registered public accounting firm may issue a report that is adverse. A material weakness could result in a restatement of our financial statements, failure to meet our reporting obligations in a timely manner, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Ineffective internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. Any of these could, in turn, result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. We have identified a material weakness in our internal controls over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company' s annual or interim financial statements will not be prevented or detected on a timely basis. We identified a material weakness in internal control related to a lack of design and maintenance of effective Information Technology General Controls, or ITGCs, over certain key financial IT systems. As a result, the related business process controls (specifically, the IT application controls and IT- dependent manual controls) that are ~~deemed~~ **dependent on the ineffective ITGCs, or that use information produced from the systems impacted by the ineffective ITGCs, were also ineffective. Although the material weakness identified above did not result in any material misstatements in our consolidated financial statements for the periods presented and there were no changes** to **previously released financial results, our management concluded that these control deficiencies constitute a material weakness and that our internal control over financial reporting was not effective as of December 31, 2024. Our management, under the oversight of the Audit Committee of our Board of Directors and in consultation with outside advisors, has begun evaluating and implementing measures designed to remediate the material weakness. In particular, we are taking steps to remediate this material weakness by (i) developing and implementing additional training and awareness programs addressing ITGCs and policies, including educating control owners concerning the principles and requirements of each control, with a focus on user access; (ii) increasing the extent of oversight and verification checks included in the operation of user access and program change management controls and processes; (iii) deploying additional tools to support administration of user access and program change management; and (iv) enhancing quarterly management reporting on the remediation measures to the Audit Committee of the Board of Directors. The above controls need to operate for a sufficient period of time so that management can conclude that our controls are operating effectively. As such, the material weakness will not** be **considered remediated until management has concluded through the implementation of these remediation measures and additional testing that these controls are effective. Additionally, a material weakness in our internal control over financial reporting has resulted in our management being unable to conclude, and any additional material weakness in our internal control over financial reporting may in the future result in our management being unable to conclude, that our disclosure controls and procedures were effective for the applicable period. We are designing and implementing new controls and measures to remediate this material weakness as noted above. However, we cannot assure you that the measures we are taking will be sufficient to remediate the material weakness or avoid the identification of additional** material weaknesses ~~we~~ **in the future. Our failure to implement and maintain effective internal control over financial reporting** could ~~face additional costs~~ **result in errors in our consolidated financial statements that could result in a restatement of our financial statements and could cause us** to ~~remedy~~ **fail to meet our periodic reporting obligations, any of which could diminish investor confidence in us and cause a decline in** ~~those~~ -- **the** ~~deficiencies, the market~~ price of our **common** stock ~~could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources~~. Provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may discourage any takeover attempts our stockholders may consider favorable, and may lead to entrenchment of management. Provisions of our amended and restated certificate of incorporation and amended and restated bylaws could delay or prevent changes in control or changes in management without the consent of the board of directors. These provisions will include the following: • a board of directors divided into three classes serving staggered three- year terms, such that not all members of the board will be elected at one time; • no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; • a prohibition on stockholder action by written consent, which means that all stockholder action must be taken at an annual or special meeting of the stockholders; • a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the Chief Executive Officer or by a majority of the total number of authorized directors; • advance notice requirements for stockholder proposals and nominations for election to the board of directors; • a requirement that no member of the board of directors may be removed from office by stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two- thirds of all outstanding shares of voting stock then entitled to vote in the election of directors; • a requirement of approval of not less than two- thirds of all outstanding shares of voting stock to amend any bylaws by stockholder action or to amend specific provisions of the certificate of incorporation; and • the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock. In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial. We will also be subject to the anti- takeover provisions contained in Section 203 of the DGCL, or Section 203. Under Section 203, a corporation

may not, in general, engage in a business combination with any holder of 15 % or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction. Our certificate of incorporation and bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees. Our certificate of incorporation and bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against it arising pursuant to any provisions of the DGCL, our certificate of incorporation or our bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The exclusive forum provision does not apply to actions arising under the Exchange Act. Our amended and restated bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act. The provision may limit a stockholder' s 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 against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in the certificate of incorporation and bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations. We do not anticipate that we will pay any cash dividends in the foreseeable future. The current expectation is that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future. An active trading market for our common stock may not ~~develop~~ **be sustained. If** ~~and~~ **an** ~~our stockholders may~~ **active trading market is** not **sustained, our ability to raise capital in the future may** be ~~able to resell~~ **impaired. Given** ~~their~~ **the** ~~shares~~ **limited trading history** of **our** common stock ~~for a profit, if at all. Prior to the merger~~, there **is a risk that an** ~~had been no public market for shares of our capital stock. An~~ active trading market for **our** shares **may not be sustained, which could put downward pressure on the market price** of our common stock ~~may never develop or be sustained. If an~~ **and thereby affect your ability to sell shares you purchased. An** ~~active~~ **inactive trading** market for our common stock ~~does not develop~~ **may also impair** ~~or~~ **our ability** ~~is not sustained, it may be difficult for our stockholders~~ to ~~sell their~~ **raise capital to continue to fund our operations by selling** shares ~~at an~~ **and impair** ~~attractive price or~~ **our** ~~at all~~ **ability to acquire other companies or technologies by using our shares as consideration**. Future sales of shares by existing stockholders could cause our stock price to decline. If our existing securityholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale discussed in our Annual Report on Form 10- K for the year ended December 31, 2023 lapse, the trading price of our common stock could decline. As of December 31, ~~2023~~ **2024**, we had ~~24~~ **29**, ~~360~~ **865**, ~~233~~ **030** shares of common stock outstanding. All outstanding shares of common stock, other than shares held by our affiliates will be freely tradable, without restriction, in the public market. In addition, shares of common stock that are subject to outstanding options of ours will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these shares are sold, the trading price of our common stock could decline. Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval. ~~Our~~ **As of December 31, 2024, our** executive officers, directors and principal stockholders, in the aggregate, beneficially ~~own~~ **owned** approximately ~~53~~ **55** % of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline. We will have broad discretion in the use of our cash ~~and~~ **,** cash equivalents **, and marketable securities** and may invest or spend our cash ~~and~~ **,** cash equivalents **, and marketable securities** in ways with which you do not agree and in ways that may not increase the value of your investment. We will have broad discretion over the use of our cash ~~and~~ **,** cash equivalents **, and marketable securities**. You may not agree with our decisions, and our use of our cash ~~and~~ **,** cash equivalents **, and marketable securities** may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our cash resources.