

Risk Factors Comparison 2025-03-27 to 2024-03-28 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K, including our financial statements and the related notes and the section titled “ Management’s Discussion and Analysis of Financial Condition and Results of Operations, ” before deciding to invest in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. We cannot assure you that any of the events discussed below will not occur. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements We are a clinical-stage biopharmaceutical company with a limited operating history. We have **incurred a history of** net losses ~~since our inception~~ and anticipate that we will ~~continue to~~ incur significant losses **for in** the foreseeable future. We have never generated any revenue from product sales and may never be profitable. We are a clinical-stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and assess our future viability. We commenced operations in October 2006, have no products approved for commercial sale and have never generated any revenue. We have devoted substantially all of our resources to organizing and staffing our company, business planning, establishing and maintaining our intellectual property portfolio, raising capital, developing our product candidates, undertaking research and development activities, and providing general and administrative support for these operations. We are conducting several clinical trials and preclinical studies for our lead product candidate, Auxora, which is currently in ~~a Phase 2b clinical trial in AP and accompanying SIRS, an ongoing~~ **Phase 2 trial in AKI with AHRF and a** Phase 1 / 2 clinical trial for which the first cohort in pediatric patients with AIPT as a side effect of pediatric acute lymphoblastic leukemia treatment with asparaginase ~~has~~. **We recently completed a Phase 2b trial for Auxora in AP and accompanying SIRS and are planning a Phase 3 trial in this indication, and we previously completed** a Phase 2 trial in COVID-19 pneumonia patients with ARDS ~~which has been completed and may inform the further development of Auxora for patients with AHRF and / or ARDS with a broad range of etiologies, and a Phase 2 clinical trial in AKI which we plan to initiate in the second quarter of 2024~~. Our other pipeline programs, which include new product candidates, are in preclinical development. ~~We~~ **As of December 31, 2024, we had an accumulated deficit of \$ 159.8 million and a net loss of \$ 13.7 million for the year ended December 31, 2024. Other than the three months ended March 31, 2024, we** have incurred net losses ~~each year since our inception. As of December 31, 2023, we had an accumulated deficit of \$ 146.1 million and a net loss of \$ 34.4 million for the year ended December 31, 2023~~. ~~We~~ **have never generated revenue from product sales and we** expect that it will be several years, if ever, before we have a product candidate ready for commercialization. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future as we advance our product candidates through clinical development. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders’ equity and working capital. To become and remain profitable, we must develop and eventually commercialize product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, finding external manufacturing capacity sufficient to meet commercial demand, marketing and selling those product candidates for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenue that is significant or large enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. We will need to obtain substantial additional funding to complete the development and any commercialization of our product candidates. If we are unable to raise this capital when needed, on acceptable terms, or at all, we may be forced to delay, reduce or eliminate the development of our product candidates or other operations. Since we commenced operations in October 2006, we have primarily financed our operations through private placements of our preferred stock, convertible promissory notes, **warrants** and common stock ~~and~~, through the Merger with Graybug **and through an underwritten public offering**. We have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially for the foreseeable future. The development of drug product candidates is highly capital intensive. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory and quality capabilities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution. Accordingly, we will 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 could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. As of December 31, ~~2023~~ **2024**, we had \$ ~~11.8~~ **2.7**

million in cash, cash equivalents and short- term investments. Based on our current operating plans, we believe our existing resources, including the ~~the funds net proceeds of \$ 9. 7 million from the Loan a private placement which had closings in January~~ and ~~Security Agreement with Avenue Venture Opportunities Fund entered into on~~ February of ~~28, 2024~~ **2025**, will be sufficient to fund our ~~current~~ operations ~~into the second half of 2025 and will allow us to fund the advancement of Auxora in AP, AIPT, and AKI through certain clinical milestones in into the middle of 2024-2026 and the first half of 2025~~. However, our current cash, cash equivalents and short- term investments will not be sufficient to fund any of our product candidates through regulatory approval, nor will it be sufficient to pursue additional indications for Auxora like AHRF, nor will it be sufficient to fund clinical trials on other product candidates in our portfolio aside from ~~the ongoing KOURAGE trial of~~ Auxora, and we will need to raise substantial additional capital to complete the development and any commercialization of our product candidates. We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to: • the progress, costs and results of our ongoing clinical trials of Auxora and our planned trials for our other product candidates; • the scope, progress, results and costs of discovery research, preclinical development, laboratory testing and clinical trials for our product candidates, including our ongoing clinical trials of Auxora; • the costs, timing and outcome of regulatory review of our product candidates; • our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient (“ API ”) and manufacture of drug product for our product candidates and the terms of such arrangements; • the costs and timing of any future commercialization activities, including product manufacturing, sales, marketing and distribution, for any of our product candidates for which we may receive marketing approval; • the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; • the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property- related claims; • the extent to which we acquire or in- license other products, product candidates, technologies or data referencing rights; • our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements; • the payment or receipt of milestones and receipt of other collaboration- based revenues, if any; • the number of, and development requirements for, other product candidates that we pursue; • the impacts of the ongoing ~~or future international~~ conflicts ~~between Ukraine and Russia and in the Middle East~~ and potential future bank failures; and • the costs of operating as a public company. Because we do not expect to generate revenue from product candidate sales for many years, if at all, we will need to obtain substantial additional funding in connection with our continuing operations and expected increases in expenses. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. The impacts of the ongoing ~~or future international~~ conflicts ~~between Ukraine and Russia and in the Middle East~~ and potential future bank failures on capital markets may affect the availability, amount and type of financing available to us in the future. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could adversely affect our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our proprietary platform or product candidates. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants further limiting or restricting our ability to take specific actions, such as limitations on our ability to incur debt, make capital expenditures or declare dividends. If we raise funds through collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our proprietary product candidate development process or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Attempting to secure additional financing may also divert our management from our day- to- day activities, which may impair or delay our ability to develop our proprietary platform. In addition, demands on our cash resources may change as a result of many factors currently unknown to us including, but not limited to, any unforeseen costs we may incur as a result of preclinical study or clinical trial delays, or disruptions in the manufacturing of our product candidates, due to the ongoing ~~or future international~~ conflicts ~~between Ukraine and Russia and in the Middle East~~, potential future bank failures or other causes, and we may need to seek additional funds sooner than planned. If we are unable to obtain funding on a timely basis or at all, we may be required to significantly curtail or stop one or more of our research or development programs. Any

acquisitions or strategic collaborations may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities or subject us to other risks. From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products and technologies, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including, but not limited to: • increased operating expenses and cash requirements; • the assumption of indebtedness or contingent or unknown liabilities; • assimilation of operations, intellectual property and products or product candidates of an acquired company, including difficulties associated with integrating new personnel; • the diversion of our management’s attention from our existing product candidates and initiatives in pursuing such an acquisition or a strategic partnership; • retention of key employees, the loss of key personnel and uncertainties about our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals, and the possibility of disagreements or disputes with such other party; and • our inability to generate revenue from acquired products, product candidates, intellectual property rights, technologies, and / or businesses sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. **On February 28, 2025 (the “ Closing Date ”), we entered into a Loan and Security Agreement (“ 2025 LSA ”) with Avenue Venture Opportunities Fund (the “ Lender ”), for (i) an initial growth capital loan in the principal amount of \$ 10, 000, 000 funded on March 3, 2025 (ii) up to \$ 7, 500, 000 to be made available to the Company between September 1, 2025 and March 31, 2026, subject to, among other things, the Company’s achievement of certain milestones with respect to certain of its ongoing clinical trials and (iii) up to \$ 15, 000, 000 to be made available to the Company between October 1, 2025 and March 31, 2026, subject to, among other things, (a) the Company’s achievement of additional milestones with respect to certain of its ongoing clinical trials and (b) the mutual written agreement of the Company and the Lender (upon its investment committee approval).** In addition, if we engage in acquisitions or strategic partnerships, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses or acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our growth or limit access to technology or drugs that may be important to the development of our business. **The terms of the 2025 LSA place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility. The 2025 LSA includes customary affirmative and negative covenants, as well as standard events of default, including an event of default based on the occurrence of a material adverse event. The negative covenants include, among others, restrictions on us transferring collateral, incurring additional indebtedness, paying cash dividends or making other distributions, making investments, creating liens, and selling assets, in each case subject to certain exceptions. These restrictive covenants could limit our flexibility in operating our business and our ability to pursue business opportunities that we or our stockholders may consider beneficial. In addition, the Lender could declare a default upon the occurrence of an event that it interprets could have a material adverse effect, as defined in the 2025 LSA. Upon the occurrence and continuance of an event of default, the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the 2025 LSA. Any declaration by the Lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. We may not have enough available cash or be able to raise additional funds through equity or debt financing to repay these outstanding obligations at the time any event of default occurs. Further, if we raise any additional capital through debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.** If we are unable to maintain our listing on Nasdaq, it could become more difficult to sell our common stock in the public market. Our common stock was previously delisted from the Nasdaq Stock Market LLC (“ Nasdaq ”) and on June 12, 2023, Nasdaq approved our application to relist our common stock and we began trading on June 14, 2023 on the Nasdaq Capital Market. If we are unable to continue to meet Nasdaq’s listing standards for any reason, our common stock could be delisted from Nasdaq. If delisted, we may seek to list our securities on a different stock exchange or, if one or more broker- dealer market makers comply with applicable requirements, the OTC. Listing on such other market or exchange could reduce the liquidity of our common stock. If our common stock were to trade in the OTC market, an investor would find it more difficult to dispose of, or to obtain accurate quotations for the price of, the common stock. A delisting from Nasdaq and failure to obtain listing on another market or exchange would subject our common stock to so- called penny stock rules that impose additional sales practice and market-making requirements on broker- dealers who sell or make a market in such securities. Consequently, removal from Nasdaq and failure to obtain listing on another market or exchange could affect the ability or willingness of broker- dealers to sell or make a market in our common stock and the ability of purchasers of our common stock to sell their securities in the secondary market. Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates Our proprietary CRAC channel inhibition science is based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval and we may not be successful in our efforts to use and expand our science to build a pipeline of product candidates. We are seeking to identify and develop a broad pipeline of product candidates using our proprietary CRAC channel inhibitor science to address acute critical illness and chronic inflammatory and immunologic diseases where there are no effective therapies. Our lead product candidate, Auxora, **is currently in recently completed a Phase 2b clinical development trial** and we have only completed **one two** randomized, blinded placebo- controlled **trial trials** with Auxora to date. We are not aware of any FDA approved therapeutics utilizing similar technology. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our proprietary CRAC channel inhibition science is both preliminary and limited. Additionally, there are no drugs currently approved for the treatment of AP and as a result the FDA has not established the endpoints that will be required for approval in this indication. As a result, we are exposed

to a number of unforeseen risks and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates. Given the novelty of our CRAC channel inhibition science, we intend to work closely with the FDA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates; however, due to a lack of relevant experience with the indications that we are pursuing, the regulatory pathway with the FDA and comparable regulatory authorities may be more complex and time-consuming. There can be no assurance as to the length of clinical development, the number of patients that the FDA may require to be enrolled in clinical trials to establish the safety and efficacy of our product candidates, or that the data generated in these clinical trials will be acceptable to the FDA to support marketing approvals. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business. Our business is highly dependent on the success of our product candidates, in particular Auxora, and we may fail to develop Auxora successfully or be unable to obtain regulatory approval. Our future success is dependent on our ability to complete clinical trials in a timely and successful manner and obtain marketing approval for and successfully commercialize Auxora, our lead product candidate. We are investing the majority of our efforts and financial resources in the research and development of Auxora for multiple indications. Auxora is currently in several studies: an ongoing Phase 2b clinical trial in AP and accompanying SIRS; an ongoing Phase 1 / 2 clinical trial, for which the first cohort **was completed**, in pediatric patients with AIPT as a side effect of pediatric acute lymphoblastic leukemia treatment with asparaginase ~~has completed~~; and a Phase 2 trial ~~in AKI that we initiated in July 2024. Auxora was also studied in a completed Phase 2b clinical trial in AP and accompanying SIRS and a completed Phase 2 trial~~ in COVID-19 pneumonia patients with ARDS which ~~has completed and~~ may inform the design of clinical development in AHRS and / or ARDS due to a broad range of etiologies ~~; and a Phase 2 trial in AKI expected to be initiated in the second quarter of 2024~~. We also have additional preclinical product candidates that will need to progress through IND application enabling studies prior to clinical development. None of our product candidates have advanced into a late-stage or pivotal trials for the indications for which we are pursuing development. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. Although certain of our employees have prior experience with clinical trials, regulatory approvals and manufacturing of pharmaceutical products, we have not previously completed any late-stage or pivotal clinical trials or submitted a **new drug application ("NDA")** to the FDA or regulatory approval filings to comparable foreign authorities for any product candidate, and Auxora may not be successful in clinical trials and may not receive any regulatory approval. The FDA and other comparable global regulatory authorities can delay, limit or deny approval of a product candidate for many reasons. Any delay in obtaining, or inability to obtain, applicable regulatory approval will delay or harm our ability to successfully commercialize Auxora and harm our business, financial condition, results of operations and prospects. Furthermore, because Auxora is our most advanced product candidate, if our clinical trials of Auxora encounter safety, efficacy or manufacturing problems, development delays, regulatory issues or other problems, our development plans for Auxora and our other product candidates in our pipeline could be significantly impaired, which could harm our business, financial condition, results of operations and prospects. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidate in late-stage clinical trials for regulatory approval or in obtaining marketing approval thereafter. Given our early stage of development, it may be several years, if at all, before we have demonstrated the safety and efficacy of a treatment sufficient to warrant approval for commercialization. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business. Clinical development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval. The research and development of drugs is extremely risky. Only a small percentage of programs that enter the clinical development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate in humans. Clinical testing is expensive, can take many years to complete and its outcome is uncertain. 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 marketing approval of their product candidates. The results of preclinical studies and early clinical **trials of product** candidates, even those with the same or similar mechanisms of action, may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. While we have previously received results, some preliminary, from **one-two** randomized, blinded placebo-controlled **trial trials**, one small blinded randomized SOC controlled trial, one small randomized open-label placebo-controlled trial, and one small open-label single site **trial, and one small open label investigator sponsored clinical** trial, we do not know how Auxora will perform in the ongoing Phase 2 clinical trials or in future clinical trials with larger sample sizes. Results of clinical trials with smaller sample sizes, such as our completed SOC-controlled Phase 2a clinical trial of Auxora in 21 patients with AP and accompanying SIRS plus hypoxemia, can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. In general, clinical trial failure may result from a

multitude of factors including flaws in trial design, dose selection, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. To date, we have not completed any **clinical trials that the FDA has confirmed or accepted as** late-stage or pivotal clinical trials for any of our product candidates. We cannot guarantee that any clinical trials will be initiated or conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of an IND or similar application will result in the FDA or other regulatory authority, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Any of these events could cause delays and interruptions in our clinical trials, which could adversely affect our business. We may experience delays in site initiation and patient enrollment, failures to comply with study protocols, delays in the manufacture of our product candidates for clinical testing and other difficulties in starting or completing our clinical trials. Other events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory agencies, the FDA or foreign regulatory authorities, on trial design or implementation;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations (“CROs”), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required institutional review board (“IRB”) or independent ethics committee (“IEC”) approval at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials;
- imposition of a clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment or equivalent foreign application or amendment, as a result of a new safety finding that presents unreasonable risk to clinical trial participants, or after a negative finding from an inspection of our clinical trial operations or study sites;
- failure by our CROs, other third parties or us to adhere to the trial protocol or good clinical practice (“GCP”);
- third-party contractors or clinical investigators becoming debarred or suspended or otherwise penalized by the FDA or other comparable foreign regulatory authorities for violations of applicable regulatory requirements;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the treatment sites, including due to supply or manufacturing related delays, being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practices (“cGMP”), regulations or other applicable requirements, or infections or cross-contaminations of our product candidates in the manufacturing process;
- delays in having subjects’ complete participation in a study or return for post-treatment follow-up;
- changes to the clinical trial protocols;
- clinical trial sites or subjects deviating from the trial protocol or dropping out of a study;
- changes in the SOC on which a clinical development plan was based, which may require new or additional trials;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization, and delays or failure by our such manufacturers or us to make any necessary changes to such manufacturing process;
- occurrence of adverse events (“AEs”) associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of an AE in a trial of the same class of agents as our product candidate conducted by other companies;
- we ~~have expanded to and plan to conduct~~ **conducted** a significant portion of our ~~ongoing~~ CARPO trial in India and, to the extent that we ~~conduct~~ clinical trials in foreign countries, the failure of enrolled subjects in foreign countries to adhere to clinical ~~protocol~~ **protocols** as a result of differences in SOC, provision of healthcare services or cultural customs;
- patients in different geographies, including foreign countries, may show differences in clinical outcomes than expected due to differences in underlying disease etiologies or genetic factors;
- conducting clinical trials in a foreign country may also present additional administrative burdens or delays associated with foreign regulatory schemes including different requirements for clinical trial protocols;
- conducting clinical trials in a foreign country may introduce political and economic risks relevant to such foreign countries;
- receiving untimely or unfavorable feedback from applicable regulatory authorities regarding the trial or requests from regulatory authorities to modify the design of a trial;
- suspensions or terminations by us, the IRBs (or the IECs) of the institutions at which such trials are being conducted, by the data safety monitoring board (“DSMB”), for such trial or by regulatory authorities due to a number of factors, including those described above;
- lack of adequate funding; ~~or~~ **changes in regulatory requirements and guidance that require amending or submitting new clinical protocols**;
- **or disruptions at the FDA and other governmental agencies caused by funding or staffing shortages**.

In addition, disruptions caused by **international** ~~the ongoing~~ conflicts ~~between Ukraine and Russia and in the Middle East~~ may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to raise capital, generate revenues from product candidate sales and enter into or maintain collaboration arrangements. For example, if enrollment in a clinical trial is slowed, certain of our expenses related to the trial would not decrease and therefore the overall costs to complete the trial would increase. In addition, if we make manufacturing changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring product candidates to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. One of our product candidates is, and potential future product candidates may be, developed for the

treatment of a pediatric population, for which safety concerns may be particularly scrutinized by regulatory agencies. Trials involving pediatric populations can be difficult to conduct, can be quite costly and, like other clinical trials, may not yield the anticipated results. In addition, pediatric trials are more dependent on a smaller number of specialized clinical trial sites, which in turn can limit site availability and make the trials more expensive to conduct. In addition, as interest in pediatric indications grows as a result of the **RACE-Research to Accelerate Cures and Equity** Act and other market forces, trial recruitment may become even more difficult due to competition for eligible patients. Moreover, it may be challenging to ensure that pediatric or adolescent patients adhere to clinical trial protocols. Moreover, principal investigators for our 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 an investigator has created a conflict of interest or otherwise affected interpretation of the study. 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 marketing approval of one or more of our product candidates. We ~~have expanded to and plan to conduct~~ **conducted** a significant portion of our ~~ongoing~~ CARPO trial in India, and regulatory authorities may not accept data from such trial or any future clinical trials we conduct outside the United States or the applicable foreign jurisdiction. We ~~have expanded to and plan to conduct~~ **conducted** a significant portion of our ~~ongoing~~ CARPO trial in India. The acceptance of trial data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable non- U. S. regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from non- U. S. clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of non- U. S. data alone unless (i) the data are applicable to the U. S. population and U. S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many non- U. S. regulatory authorities have similar approval requirements. In addition, such non- U. S. trials would be subject to the applicable local laws of the non- U. S. jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable non- U. S. regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable non- U. S. regulatory authority does not accept such data or believes that additional data is necessary to supplement 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 product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction. Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with: • additional foreign regulatory requirements; • foreign exchange fluctuations; • compliance with foreign manufacturing, customs, shipment and storage requirements; • the failure of enrolled subjects in foreign countries to adhere to clinical protocol as a result of differences in SOC; • cultural differences in medical practice and clinical research; and • diminished protection of intellectual property in some countries. We depend on enrollment of patients in our clinical trials for our product candidates. If we experience delays or difficulties enrolling patients in our clinical trials, our research and development efforts and business, financial condition, results of operations and prospects could be adversely affected. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients to participate in each study. These trials may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, subject withdrawal from the trial or AEs. These types of developments could cause us to delay the trial or halt further development. Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. In addition, there may be limited patient pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a clinical trial. Participant enrollment in clinical trials depends on many factors, including: • the size and nature of the patient population; • the severity of the disease under investigation; • eligibility criteria for the trial; • the proximity of patients to clinical sites; • the design of the clinical protocol; • the ability to obtain and maintain research subject consents; • the ability to recruit clinical trial investigators with the appropriate competencies and experience; • the availability of competing clinical trials; • patients' perceptions of risk in traveling to clinical sites (for patients in non- hospitalized clinical trial settings); • the availability of new drugs approved for the indication the clinical trial is investigating; and • clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies. These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost- effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Preliminary, interim and topline data from our clinical trials may change as more participant data **become becomes** available, and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies and 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 as participant enrollment and treatment continues and more data become available. Our data to date is based on a small number of subjects, and as a result, data from additional subjects can have a significant impact on the overall data viewed as a whole. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business prospects. We may also announce topline data following the completion of a preclinical study or clinical trial, which may be subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available. Further, others, including regulatory agencies, 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 impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to be material or otherwise appropriate information to include in our disclosure. If the interim, top- line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. SAEs, undesirable side effects or other unexpected properties of our product candidates could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate. As we continue developing Auxora and initiate clinical trials of our additional product candidates, **Serious Adverse Events (“SAEs”)**, undesirable side effects, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective or in which efficacy is more pronounced or durable. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to our therapies. Because of our planned dose escalation design for our clinical trials, undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Additionally, results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, which may stem from our product candidates specifically or may be due to an illness from which the clinical trial subject is suffering. If unacceptable side effects arise in the development of our product candidates such that there is no longer a positive benefit risk, we, the FDA, the IRBs at the institutions in which our trials are conducted or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials 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 subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, and inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Even if we believe our product candidates initially show promise in early clinical trials, side effects of product candidates may only be detectable after they are tested in larger, longer and more extensive clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor. If serious adverse or unexpected side effects are identified during development or after approval (including pursuant to any toxicity studies, including reproductive toxicity studies) and are determined to be attributed to our product candidates, we may be required to develop a Risk Evaluation and Mitigation Strategy (“REMS”) to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Product- related side effects could also result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations and prospects. In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such product candidates, a number of potentially significant negative consequences could result, including: • regulatory authorities may suspend, withdraw or limit approvals of such product candidate, or seek an injunction against its manufacture or distribution; • regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product candidate; • we may be required to create a medication guide outlining the risks of such side effects for distribution to patients; • we may be required to change the way a product candidate is administered or conduct additional clinical trials; • the product candidate may become less competitive; • we may decide to remove the product candidate from the marketplace; and • we may be subject to fines, injunctions or the imposition of civil or criminal penalties. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could seriously harm our business. We may seek special designations by the regulatory

authorities to expedite regulatory approvals, but may not be successful in receiving such designations, and even if received, they may not benefit the development and regulatory approval process. We may seek various designations by the regulatory authorities for any product candidates that we develop, such as Fast Track designation or Breakthrough Therapy designation. If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for Fast Track designation from the FDA. The sponsor of a product candidate with Fast Track designation has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the candidate may be eligible for priority review if the relevant criteria are met. A product candidate with Fast Track designation may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. We have received Fast Track designation for Auxora for the treatment of AP, and we may receive Fast Track designation for other product candidates in the future; however, we may not experience a faster development process, review or approval compared to conventional FDA approval timelines, and the FDA may still decline to approve Auxora or our other designated product candidates. The FDA may rescind the Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program or for any other reason. A Breakthrough Therapy is defined by the FDA 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, may demonstrate substantial improvement over currently approved 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. The designation also includes all of the Fast Track designation benefits, including eligibility for rolling review of an NDA submission. Seeking and obtaining these designations is dependent upon results of our clinical program, and whether and when we may have the data from our clinical programs to support an application to obtain any such designation is uncertain. Even if we do receive the designations we may apply for, we may not experience a faster development process, review or approval compared to conventional FDA or similar foreign regulatory authorities' procedures, as applicable. The FDA or similar foreign regulatory authorities, as applicable, may rescind any granted designations if it believes that the designation is no longer supported by data from our clinical development program. We may seek orphan drug designation for 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. 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 as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug 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 grants orphan drug designation after receiving the opinion of the **European Medicines Agency ("EMA")** Committee for Orphan Medicinal Products on an orphan drug designation application. Orphan drug designation is intended to promote the development of drugs that are (1) intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (2) either (a) affecting not more than five in 10,000 persons in Europe, or (b) when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug; and (3) for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or if such a method exists, the product will be of significant benefit to those affected by the condition). In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor. We have received orphan drug designation for Auxora for the treatment of AP in the European Union, and we may receive orphan drug designation for other product candidates in the future; however, we may not experience a faster development process, review or approval compared to conventional approval timelines, and the European Commission and EMA may still decline to approve Auxora or our other designated product candidates. The European Commission and EMA may rescind the orphan drug designation if it believes that the designation is no longer supported by data from our clinical development program or for any other reason. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same or similar drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if, at the end of the fifth year, it is established that the drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified. Even if we obtain orphan drug exclusivity for any of our product candidates that obtain approval, that exclusivity may not effectively protect those product candidates from competition because different therapies can be approved for the same condition. Even after an orphan drug is approved, the FDA or comparable foreign authorities can subsequently approve another drug for the same condition if the relevant authority concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. 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 drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek orphan drug designation for applicable indications for our product candidates, we may never receive such designations. Even if we do receive such designations, we may not enjoy the benefits of those designations. We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA **or other regulatory authorities**, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA **or foreign regulatory authorities** may seek to withdraw accelerated approval. We may in the future seek an accelerated approval for our one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that such product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to ~~verify~~ **verify** and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug. Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e. g., breakthrough therapy designation) for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates would result in a longer time period to commercialization of such product candidates, if any, could increase the cost of development of such candidates and could harm our competitive position in the marketplace. Our product candidates must meet extensive regulatory requirements before they can be commercialized and any regulatory approval may contain limitations or conditions that require substantial additional development expenses or limit our ability to successfully commercialize our product candidates. The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. To date, we have not submitted an NDA or other marketing authorization application to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any product candidates. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. In particular, because we are seeking to identify and develop product candidates using new technologies, there is heightened risk that the FDA or other regulatory authorities may impose additional requirements prior to granting marketing approval, including enhanced safety studies or monitoring. Furthermore, as more product candidates within a particular class of products proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including: • such authorities may disagree with the design or implementation of our clinical trials; • negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval; • serious and unexpected product candidate-related side effects may be experienced by participants in our clinical trials; • serious and unexpected results from preclinical toxicity studies that will be completed in conjunction with late stage clinical trials; • the population studied in the clinical trial may not be sufficiently broad

or representative to assure safety in the full population for which we seek approval; • such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the SOC is potentially different from that of the United States; • we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks; • such authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of an application for regulatory approval or other submissions or to obtain regulatory approval in the United States or elsewhere and such authorities may impose requirements for additional preclinical studies or clinical trials; • such authorities may disagree regarding the formulation, labeling and / or the specifications of our product candidates; • approval may be granted only for indications that are significantly more limited than what we apply for and / or with other significant restrictions on distribution and use; • such authorities may ~~fail to approve any required companion diagnostics to be used with our product candidates; • such authorities may~~ find deficiencies in the manufacturing processes or facilities of our or our third- party suppliers or manufacturers with which we or any of our potential future collaborators contract for clinical and commercial supplies; or • the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval. With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product candidate testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new products based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Even if we eventually complete clinical trials and receive approval to commercialize our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and / or the implementation of a REMS. The FDA or the comparable foreign regulatory authority also may approve a product candidate for a more limited indication or patient population than we originally requested or may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Manufacturers of our product candidates and manufacturers' facilities are also required to comply with cGMP regulations and other similar regulatory requirements, which include requirements related to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture our product candidates, if approved, and these facilities are subject to continual review and periodic inspections by the FDA and other comparable foreign regulatory authorities for compliance with cGMP regulations and other similar regulatory requirements. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and could adversely impact our business, financial condition, results of operations and prospects. We will need to obtain FDA approval of any proposed product names, including Auxora, and any failure or delay associated with such approval may adversely affect our business. Any name we intend to use for our current or future product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the United States Patent and Trademark Office ("USPTO"). The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we would lose any goodwill or brand recognition developed for previously used names and marks as well as the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates. Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. If the FDA, EMA or any other comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration requirements and continued compliance with cGMPs and GCP requirements, for any clinical trials that we conduct post- approval. In addition, any regulatory approvals that we receive for our present or future product candidates may 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 testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require REMS as a condition of approval of our product candidates, which could entail requirements for long- term patient follow- up, 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. Later discovery of previously unknown problems with a product candidate, including AEs 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 our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials; • restrictions on the marketing or manufacturing of the product candidate, withdrawal of the product candidate from the market, or voluntary or mandatory product candidate recalls; • fines, untitled or warning letters or holds on clinical trials; • refusal by the FDA, the EMA or any other comparable foreign regulatory authority

to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product candidate approvals; • product candidate seizure or detention, or refusal to permit the import or export of product candidates; and • injunctions or the imposition of civil or criminal penalties. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our or our collaborators' ability to commercialize our product candidates, and harm our business, financial condition, results of operations and prospects. Manufacturers and manufacturers' facilities are required to comply with extensive FDA and other regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application and previous responses to inspectional observations made by regulatory authorities. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. 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 be subject to enforcement action and we may not achieve or sustain profitability. 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, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product' s approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to significant liability. The U. S. 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 government has also required that companies enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which could adversely affect our business, financial condition, results of operations and prospects. Disruptions at the FDA and other government agencies caused by funding shortages, **statutory, regulatory and policy changes**, or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, **including executive orders**, the FDA' s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies such as the EMA, following its relocation to Amsterdam and corresponding staff changes, that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown or slowdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. We may not identify or discover other product candidates and may fail to capitalize on our proprietary platform or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success. Our business depends upon our ability to identify, develop and commercialize product candidates. A key element of our strategy is to discover and develop additional product candidates based upon our CRAC channel inhibitor science. We are seeking to do so through our internal research programs, and may also explore strategic collaborations for the discovery of new product candidates. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. In addition, targets for different indications may require changes to our manufacturing processes, which may slow down development or make it impossible to manufacture our product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following: • the research methodology or technology platform used may not be successful in identifying potential product candidates; • competitors may develop alternatives that render our product candidates obsolete or less attractive; • we may choose to cease development if we determine that clinical results do not show promise; • product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights; • a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; and • a product candidate may not be accepted as safe and effective by patients, the medical community or third- party payors. Because we have limited resources, we must choose to pursue and fund the development of specific types of treatment, or treatment for a specific indication, and we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for our product candidates could be inaccurate, and if we do not accurately evaluate the

commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement. If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidate programs in clinical trials and may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidate programs caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidate that we may develop; • loss of revenue; • substantial monetary awards to trial participants or patients; • significant time and costs to defend the related litigation; • withdrawal of clinical trial participants; • increased insurance costs; • the inability to commercialize any product candidate that we may develop; and • injury to our reputation and significant negative media attention. Any such outcomes could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Manufacturing, Commercialization and Reliance on Third Parties We rely on third parties to conduct and perform most of our research, preclinical studies and clinical trials. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements, fail to meet projected clinical trial enrollment schedules or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects. We do not have the ability to conduct most aspects of our preclinical studies or clinical trials in-house. As a result, we are and expect to remain dependent on third parties to conduct or otherwise support our ongoing clinical trials and any future clinical trials of our product candidates. Specifically, CROs, clinical investigators, and consultants play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the member states of the EEA, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the 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. In addition, our clinical trials must be conducted with investigational product produced under cGMP regulations (and similar foreign requirements). Our failure to comply with these regulations may require us to stop and / or repeat clinical trials, which would delay the marketing approval process. CROs, clinical trial investigators or other third parties on which we rely may not devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or any comparable foreign regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. Further, under certain circumstances, these third parties may terminate their agreements with us upon as little as 30 days prior written notice. Entering into arrangements with alternative CROs, clinical trial investigators or other third parties involves additional cost and requires management focus and time, in addition to requiring a transition period when a new CRO, clinical trial investigator or other third party begins work. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing 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. In addition, with respect to investigator-sponsored trials that are being ~~conducting~~ **conducted with Auxora (the CRSPA trial with SJCRH)** and may be conducted in the future, we do not and would not control the design or conduct of these trials, and it is possible that the FDA will not view these investigator-sponsored trials as providing adequate support for future clinical trials or market approval, 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. We expect that such arrangements will 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 submissions, 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. 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 firsthand 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 ourselves may be adversely affected. The investigators may design clinical trials with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results compared to clinical trials that we may design on our own. Negative results in investigator- sponsored clinical trials could have a material adverse effect on our efforts to obtain regulatory approval for our product candidates and the public perception of our product candidates. Additionally, the FDA may disagree with the sufficiency of our right of reference to the preclinical or clinical data generated by these investigator- sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator- sponsored trials. If so, the FDA may require us to obtain and submit additional preclinical or clinical data. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. We contract with third parties for the manufacturing and supply of certain goods and services for our product candidates for use in preclinical studies and clinical trials, which supply may become limited or interrupted or may not be of satisfactory quality and quantity. We do not have any manufacturing facilities. We produce in our laboratory relatively small quantities of product for evaluation in our research programs. We rely on third parties for the manufacture of most of our product candidates for preclinical testing and all of our product candidates for clinical testing and we will continue to rely on such third parties for commercial manufacture if any of our product candidates are approved. We currently have limited manufacturing arrangements for preclinical and clinical trial materials for each of our product candidates, including Auxora, and one component of the latter is provided by a single source supplier in China, and will continue to be for the intermediate future. In addition, our single source supplier in China and any other foreign suppliers we may utilize in the future may be subject to U. S. legislation, **including the similar to what is proposed in the BIOSECURE Act considered by Congress in 2024**, sanctions, trade restrictions and other foreign regulatory requirements, which may limit, delay, prevent or impair our ability to obtain preclinical and clinical trial materials for our product candidates. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. Furthermore, all entities involved in the preparation of product candidates for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA on a timely basis and must adhere to the FDA's GLP regulations and cGMP regulations enforced by the FDA through its facilities inspection program. Comparable foreign regulatory authorities may require compliance with similar requirements. Our facilities and quality systems, and those of our third- party contract manufacturers, must pass a pre- approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing activities of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations, although the FDA will hold us responsible for any such non- compliance with respect to our product candidates and any future approved products. In the event that any of our contracted third parties fails to comply with such requirements or to perform their obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, **including due to the ongoing or future international conflicts between Ukraine and Russia and in the Middle East** or other geopolitical or macroeconomic **conditions**, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third- party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of a third- party contractor could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture a certain aspect of our product candidates may be unique or proprietary to the third- party performing such process and we may have difficulty transferring such skills or technology to another third- party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if we attempt to establish new third- party arrangements for these product candidates or methods. If we are required to or voluntarily change a third- party contractor for any reason, we will be required to verify that the new third party maintains facilities, processes and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget. Our or a third- party's failure to execute on our manufacturing and supply requirements, do so on commercially reasonable terms and comply with cGMP could

adversely affect our business in a number of ways, including: • in the event of approval, to initiate or continue clinical trials of our product candidates; • delays in submitting regulatory applications, or receiving marketing approvals, for our product candidates; • loss of the cooperation of future collaborators; • subjecting our or any third- party manufacturing facilities to additional inspections by regulatory authorities; or • requirements to cease development to market and commercialize our product candidates, an inability to meet commercial demands for our current or any other future product candidates, if approved. Any approved product candidates may fail to achieve the degree of market acceptance by physicians, patients, hospitals, healthcare payors and others in the medical community necessary for commercial success. If any of our product candidates receives marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. Our CRAC channel inhibitors are a relatively novel technology, and no CRAC channel inhibitor- based therapy has been approved to date. Public perception may be influenced by third- party claims, such as claims that CRAC channel inhibitors are unsafe, ineffective and, consequently, our approach may not gain the acceptance of the public or the medical community. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including: • efficacy and potential advantages compared to alternative treatments; • our ability to offer our product candidates for sale at competitive prices; • convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the availability of coverage and adequate reimbursement by third- party payors, including government payors, for our products, if approved by applicable regulatory authorities; • the strength of marketing and distribution support; and • the prevalence and severity of any side effects. For example, Auxora is an injectable emulsion drug product that must be administered intravenously over four hours, and this dosing regimen may be inconvenient for **some** physicians or patients. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. We may not be able to successfully commercialize our product candidates due to unfavorable pricing regulations or third- party coverage and reimbursement policies, which could make it difficult for us to sell our product candidates profitably. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third- party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our product candidates. Therefore, coverage and adequate reimbursement are critical to a new product' s acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, there is no uniform policy among third- party payors for coverage and reimbursement. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Therefore, one third- party payor' s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Coverage and reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor' s determination that use of a product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational. Obtaining coverage and reimbursement approval for a product from a government or other third- party payor is a time- consuming and costly process, with uncertain results, that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our product candidates to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved product candidates, and coverage may not be available, or may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States. Reimbursement may not be available for any product that we commercialize and, if coverage and reimbursement are available, the level of reimbursement may not be adequate. Obtaining reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Additionally, we expect our future products to potentially be more expensive than other therapeutics due to the personalized and proprietary product selection process of our product candidates, as well as our individualized approach to patient treatment, which requires patient hospitalization, in some cases intensive care unit admission and the potential administration of combination therapies, all of which increases costs and may result in reimbursement payment rates which may not be adequate or may require co- payments that patients find unacceptably high. Our inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payors for any approved product candidates that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition. Further, coverage policies and third- party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further,

from time to time, the Centers for Medicare & Medicaid Services (“ CMS ”) revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System, which may result in reduced Medicare payments. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product. Outside of the United States, many countries require approval of the sale price of a product before it can be marketed, and the pricing review period only begins after marketing or product licensing approval is granted. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Member states are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost- effectiveness of a particular product candidate to currently available therapies. To obtain reimbursement or pricing approval in some of these countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate to other available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, new products are facing increasingly high barriers to entry. In addition, in some countries, cross- border imports from low- priced markets exert a commercial pressure on pricing within a country. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval. If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved. We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these such product revenue to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such product candidates outside of the United States, which would limit our ability to realize their full market potential. In order to market any product candidates outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our product candidates will be harmed.

Risks Related to Our Industry and Business Operations We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan. Our ability to compete in the highly

competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We conduct substantially all of our operations at our facility in La Jolla, California. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with certain of our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key person” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. Dr. Rachel Leheny, our Chief Executive Officer and a member of our Board of Directors, and Eric W. Roberts, our Chief Business Officer and a member of our Board of Directors, also provide services for Valence, an investment fund that is one of our significant stockholders. Our Chief Executive Officer and member of our Board of Directors, Dr. Leheny, and our Chief Business Officer and member of our Board of Directors, Mr. Roberts, are the co-founders of Valence Life Sciences (“Valence”), are employed as managing directors of Valence and beneficially own the shares of the company held by Valence. Entities affiliated with Valence together with Dr. Leheny and Mr. Roberts beneficially ~~owned~~ **own a significant portion** ~~approximately 14.3%~~ **approximately 14.3%** of our common stock ~~as of March 21, 2024~~. Although we expect that each of Dr. Leheny and Mr. Roberts will devote on average at least 40 hours per week to our company and remain highly active in our management, they will also continue to devote time to Valence. Because Dr. Leheny and Mr. Roberts are not required to work exclusively for us, their attention to other activities could slow our operations, which could adversely affect our business. In addition, although we do not believe Valence currently has any investments that conflict with our interests, in the future Valence may invest in companies that may compete with us for business opportunities or develop products that are competitive with ours. As a result, Dr. Leheny’s and Mr. Roberts’ interests may not be aligned with the interests of our other stockholders, and they may from time to time be incentivized to take certain actions that benefit their other interests and that our other stockholders do not view as being in their interest as investors in our company. We expect to expand our development, regulatory and operational capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As of December 31, ~~2023~~ **2024**, we employed 14 full-time employees, seven of whom were primarily engaged in research and development activities. We also engage various consultants that are primarily engaged in research and development activities. As we advance our research and development programs, we may be required to further increase the number of our employees, particularly in the areas of clinical development, quality, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage any future growth, we must:

- identify, recruit, integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our product candidates, both as a monotherapy and combination therapy; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our need to effectively execute our growth strategy requires that we:

- discover new product candidates, develop the process and analytical methods for IND-enabling studies and regulatory submissions, complete the required IND-enabling studies for each, and receive approval from the FDA and other regulatory authorities to initiate clinical trials for such product candidates;
- manage our clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees;
- maintain sufficient quantities of drug product for clinical supply and establish manufacturing capabilities or arrangements with third-party manufacturers for commercial supply, if and when approved; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals. Furthermore, the United States is currently experiencing an increasingly competitive labor market and we are uncertain as to the employment environment in the future, or how that environment will impact our workforce, including our ability to hire or retain qualified employees, consultants, contractors or other key personnel to facilitate our growth. We face substantial competition, which may result in others discovering, developing or commercializing product candidates more quickly or marketing them more successfully than us. The development and commercialization of new product candidates is highly competitive. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop therapies for the treatment of acute critical illnesses. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more

convenient, or are less expensive than any product candidates that we may develop or that would render any product candidates that we may develop obsolete or non-competitive. Our competitors also may obtain marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Moreover, with the proliferation of new drugs and therapies into critical illnesses, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical. The amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for product candidates will likely need to show a risk benefit profile that is competitive with or more favorable than products approved prior to ours in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those product candidates or product candidate candidates, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product business, financial condition, results of operations and prospects could be adversely affected. There is significant investment across the biotechnology and pharmaceutical industries in developing novel and proprietary therapies for acute critical illnesses. We face substantial and increasing competition on multiple fronts, including from larger companies with access to more resources and capital, as well as more experience in research and development, clinical trials and commercialization. Smaller or earlier-stage companies as well as academic institutions, government agencies and public and private research institutions may also prove to be significant competitors. Additionally, we may face competition in hiring scientific and management personnel, establishing clinical trial sites, recruiting patients to participate in clinical trials and acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience, price and degree of reimbursement. 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 and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and subject enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. The key competitive factors affecting the success of all of our programs are likely to be the possibility of other companies developing drugs that address the same **illnesses-disease indications** that we are aiming to address. Some of these markets are limited and significant competition could reduce the number of patients we are able to reach. If we are not successful in developing, commercializing and achieving higher levels of reimbursement than our competitors, we will not be able to compete against them and our business would be adversely affected. We may wish to form collaborations in the future with respect to our product candidates, but may not be able to do so or realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans. The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We may, in the future, decide to collaborate with other biopharmaceutical companies for the development and potential commercialization of those product candidates, including in territories outside the United States or for certain indications. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third-party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third-party. Our ability to 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 evaluation of our technologies, product candidates and market opportunities. 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 candidates. We may also be restricted under any license agreements from entering into agreements on certain terms or at all 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 and changes to our strategies. As a result, 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 such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing 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. Our product candidates may also require specific components

to work effectively and efficiently, and rights to those components may be held by others. We may be unable to in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. 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. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products. 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. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with Auxora and any future product candidates;
- a collaborator with marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development, or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Failure to comply with applicable data protection laws, regulations, and other obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and mass arbitration demands, and / or adverse publicity and could negatively affect our operating results and business. We and ~~any potential collaborators~~ **the third parties with whom we work** may be subject to federal, state, and foreign data protection laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations that address privacy and data security. In the United States, numerous federal, state, and local laws and regulations, including federal and state health information privacy laws, state data breach notification laws, personal data protection laws, federal, state, and local consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws ~~that govern the collection, use, disclosure, and protection of health-related and other personal data~~ **could apply to our operations or the operations of our collaborators**. In addition, we ~~may~~ obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under federal HIPAA, as amended by the HITECH. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use, or disclose individually identifiable protected information provided by a HIPAA-covered entity or business associate in a manner that is not authorized or permitted by HIPAA. Additionally, new privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. For example, the CCPA requires covered companies to provide certain disclosures to California consumers (including business representatives and employees who are California residents) and provide such consumers data protection and privacy rights, including the ability to opt-out of certain sales or sharing of personal data. The CCPA provides for administrative penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal data. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CPRA expanded the CCPA's requirements, including by adding a ~~new~~ **new** right for consumers to correct their personal ~~information~~ **data** and establishing a ~~new~~ **new** regulatory agency to implement and enforce the law. Moreover, **a number of** other states ~~such as Virginia and Colorado,~~ have enacted data protection laws, and similar laws are being considered in several other states, as well as at the federal and local levels. Although these laws ~~may~~ exempt some data processed in the context of clinical trials, these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products and services involving data are offered, all of which may harm our business, financial condition, results of operations and prospects. Internationally, virtually every jurisdiction in which we operate has established its own data security and privacy legal framework that may also apply to health-related and other personal data obtained outside of the United States. For example, the EU **has adopted the EU GDPR** and the United Kingdom ~~have~~ **has** adopted the **UK** General Data Protection Regulation (**collectively**, "EU-GDPR" and "UK-GDPR," respectively), which imposes strict requirements for processing the personal data of individuals within the EEA and the United Kingdom. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to 20 million euros, 17.5 million pounds sterling under the UK GDPR, or in each case, up to 4% of the annual global revenue of the noncompliant company, whichever is greater, as well as private litigation related to the processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data. Although there are currently various

mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, the United Kingdom's International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA or, the United Kingdom, or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and United Kingdom to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. In addition, the new India Digital Personal Data Protection Act 2023 (" DPDP ") is likely to come into force in 2024. Like the GDPR, the DPDP has extra- territorial reach and failure to comply with the DPDP may lead to substantial fines. A significant portion of our ongoing CARPO trial was is being conducted in India and we and certain third parties upon with whom we work may be subject to the DPDP. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, clinical trial subjects about whom we or the third parties with whom we work obtain information, as well as the providers who share this information with us, contractually limit our ability to use and disclose the information. We publish privacy policies, marketing materials, whitepapers, and other statements such as statements related to compliance with certain certifications or self- regulatory principles, concerning data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may we rely will be subject to inconsistent or conflict among jurisdictions. Preparing for and complying with the these DPDP when it becomes effective obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Failure by us or third parties upon which with whom we rely work to comply with U. S. and international data protection laws, regulations, and other obligations could result in significant consequences, including without limitation government enforcement actions (which could include investigations, civil or criminal penalties, audits inspections), private litigation or mass arbitration demands, additional reporting requirements or oversight, bans on processing personal data, data breach reporting requirements 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 or contractual privacy 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. Our information technology systems, or those of our CROs, contractors, consultants, or other contractors or consultants third parties with whom we work, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business. We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal data, including health- related information) (collectively, " sensitive information "). As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, which could result in material adverse impacts to our business, including the theft of our intellectual property- sensitive information, have increased in frequency and sophistication. Despite our implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our information technology systems and those of our third- party CROs, contractors, consultants, and other contractors and consultants third parties with whom we work are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, sophisticated nation- state and nation- state supported actors, and / or other third parties, or from cyber- attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering attacks, malicious code, credential stuffing attacks, credential harvesting, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, attacks enhanced or facilitated by AI, and other means to affect service reliability and threaten the confidentiality, integrity and availability of our sensitive information), which may compromise our or our- the third party partners- parties with whom we work system- systems infrastructure or lead to data leakage. For example, we have experienced phishing attacks in the past and we may be a target of phishing attacks or other cyber- attacks in the future. In

particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive **data-information** and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. To the extent that any disruption or security breach were to result in a loss of, or damage to, our **data-sensitive information** or applications (or those of ~~our the third-party partners~~ **parties with whom we work**), or inappropriate disclosure of **confidential-sensitive** information, we could incur liability and reputational damage, and the further development and commercialization of our product candidates could be delayed. **It may be difficult or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.** We also have outsourced elements of our operations to third parties, and as a result we manage a number of third ~~parties~~ **parties** ~~party contractors~~ who have access to our **confidential-sensitive** information. We rely on these third ~~parties~~ **parties** ~~party service providers~~ and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If ~~our the third-party service providers~~ **parties with whom we work** experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if ~~our the third-party service providers~~ **parties with whom we work** fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or ~~our the third-party partners~~ **parties with whom we work** supply chains have not been compromised. While we invest in our information security systems, we cannot assure you that our data protection efforts and our investment in information technology will prevent breakdowns, data leakages, breaches in our systems or other cyber incidents that could have an adverse effect upon our reputation, business, financial condition, results or operations and prospects. We may not be successful in preventing or detecting cyber-attacks or mitigating their effects, or we may be perceived as having failed to do so. We take steps **designed** to detect, **mitigate** and remediate vulnerabilities **in our information systems (such as hardware and / or software, including that of the third parties with whom we work)**, but we ~~may have not~~, **and in the future may not, however**, be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities, **including on** could be exploited but may not be detected until after a **timely basis security incident has occurred. Unremediated high risk or critical vulnerabilities pose material risks to our business.** Further, we **have (and may in the future) experience experienced** delays in developing and deploying remedial measures **and patches** designed to address any such identified vulnerabilities. **Vulnerabilities [could] be exploited and result in a security incident**. For example, if a cyber-attack were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and / or unauthorized access, use, or disclosure of, or the prevention of access to, **confidential-sensitive** information (including trade secrets or other intellectual property, proprietary business information, and personal data), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal data, including personal data regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and / or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal data, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business **(and that of the third parties with whom we work)**. We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters, terrorism or similar unforeseen events and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Our headquarters and main research facility are located in California near major earthquake faults and fire zones. If earthquakes, fires, other natural disasters, terrorism or similar unforeseen events beyond our control prevent us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe AEs. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. As of December 31, ~~2023~~ **2024**, we had federal and state net operating loss ("NOL") carryforwards of approximately \$ ~~278-296.78~~ **7.8** million and ~~nil~~, **respectively, \$ 103-102.25** million, ~~respectively, \$ 74.6~~ million of our federal NOLs were generated prior to 2018 and will begin to expire in 2026, unless previously utilized, but may be used to offset up to 100 % of future taxable income before expiration. Under current law, our federal NOLs generated in tax years beginning after

December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80 % of taxable income. It is uncertain if and to what extent various states will conform to federal tax law. We also have federal and state research and development credit carryforwards totaling \$ 12.13. 4.3 million and \$ 2.3. 4.1 million, respectively. The federal research and development credit carryforwards will begin to expire in 2027, unless previously utilized. The state research and development credits do not expire. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the “ Code ”), and corresponding provisions of state law, if a corporation undergoes an “ ownership change, ” which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three- year period, the corporation’ s ability to use its pre- change NOL carryforwards and certain other tax attributes to offset its post- change income or taxes may be limited. This could limit the amount of NOLs or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. We have not undertaken a Section 382 study, and it is possible that we have previously undergone one or more ownership changes so that our use of net operating losses is subject to limitation. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre- change NOLs to offset U. S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows. Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations. New income, sales, use, or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified, or applied adversely to us. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (the “ Tax Act ”), the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act (“ IRA ”) enacted many significant changes to the U. S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one- time charges, and could increase our future U. S. tax expense. Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations. In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post- approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, including in the EU, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the “ Affordable Care Act ”), substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the U. S. pharmaceutical industry. As another example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive healthcare provisions and amendments to existing laws, including a requirement that all manufacturers of drugs and biological products covered under Medicare Part B report the product’ s average sales price, or ASP, to Department of Health and Human Services (“ HHS ”) beginning on January 1, 2022, subject to enforcement via civil money penalties. Since its enactment, there have been **amendments to and** judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act. **For** By way of example , the Tax Act repealed penalties for not complying with the Affordable Care Act’ s individual mandate to carry health insurance, commonly referred to as the “ individual mandate. ” Following several years of litigation in the federal courts, in June 2021 the U. S. Supreme Court upheld the Affordable Care Act when it dismissed a legal challenge to the Affordable Care Act’ s constitutionality on procedural grounds following that legislative repeal of the individual mandate. It is possible that the Affordable Care Act will be subject to additional challenges in the future. Prior to the Supreme Court’ s decision, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. Further, on August 16, 2022, **President Biden the IRA was** signed the IRA into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the “ donut hole ” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost through a newly established manufacturer discount program. It is unclear how any such challenges and the healthcare reform measures of the **Biden second Trump** administration will impact the Affordable Care Act, our business, or financial condition. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted that affect healthcare expenditures. These changes include aggregate reductions to Medicare payments to providers of 2 % per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to legislative amendments to the statute, will remain in effect until 2032, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals,

and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. In addition, new laws may result in additional reductions in Medicare and other healthcare funding, which may adversely affect customer demand and affordability for our product candidates and, accordingly, the results of our financial operations. Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries, presidential executive orders, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. ~~At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. Moreover, in July 2021, President Biden issued a sweeping executive order on promoting competition in the American economy that includes several mandates pertaining to the pharmaceutical and healthcare insurance industries. Among other things, the executive order includes several directives regarding the Federal Trade Commission's oversight of potentially anticompetitive practices within the pharmaceutical industry. The executive order also directs the FDA to work towards implementing a system for importing drugs from Canada (following on a Trump administration notice and comment rulemaking on Canadian drug importation that was finalized in October 2020).~~ On January 5, 2024, the FDA approved Florida's Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. ~~At In response to President Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these~~ ~~the federal level~~ principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs ~~and biologics that have been on the market for at least 7 years~~ covered under Medicare (the "**Medicare Drug Price Negotiation Program**") and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions ~~began to~~ take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the ~~list of~~ **list-agreed-upon prices** of the first ten drugs that ~~were~~ will be subject to price negotiations, although the Medicare ~~Drug Price Negotiation Program~~ **Drug Price Negotiation Program** is currently subject to legal challenges. ~~The IRA permits~~ **On January 17, 2025, HHS selected fifteen additional products covered under Part D to implement many of these provisions through guidance, as opposed to regulation, for the initial price negotiation in 2025. Each year thereafter more Part B and Part D products will continue to become subject to issue and update guidance as these** ~~the Medicare Drug Price Negotiation programs~~ **Program** as implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, ~~the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act~~ **was announced**. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. For example, California requires pharmaceutical manufacturers to notify certain purchasers, including health insurers and government health plans at least 60 days before any scheduled increase in the wholesale acquisition cost ("WAC"), of their product if the increase exceeds 16%, and further requires pharmaceutical manufacturers to explain whether a change or improvement in the product necessitates such an increase. Similarly, Vermont requires pharmaceutical manufacturers to disclose price information on certain prescription drugs, and to provide notification to the state if introducing a new drug with a WAC in excess of the Medicare Part D specialty drug threshold. In December 2020, the U. S. Supreme Court also held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers, or PBMs, and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. ~~We expect that these and other healthcare reform measures that may be adopted in the future~~ **, particularly in light of the recent U. S. Presidential and Congressional elections,** may result in more rigorous coverage criteria and lower reimbursement and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost-containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once marketing approval is obtained. In the European Union, coverage and reimbursement status of any product candidates for which we obtain regulatory approval are provided for by the national laws of member states. The requirements may differ across the EU member states. Also, at national level, actions have been taken to enact transparency and anti-gift laws (similar to the US Physician Payments Sunshine Act) regarding payments between pharmaceutical companies and health care professionals. We are subject to applicable fraud and abuse, transparency, government price reporting, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face

substantial penalties. Healthcare providers and third- party payors will play a primary role in the recommendation and prescription of any future product candidates we may develop and any product candidates for which we obtain marketing approval. Our current and future arrangements with clinical investigators, third- party payors, healthcare provider and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we research, market, sell and distribute our product candidates. The laws that may affect our ability to operate include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term “ remuneration ” has been broadly interpreted to include anything of value. The federal Anti- Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, and purchasers, on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but these exceptions and safe harbors are narrowly drawn. Practices that are alleged to be intended to induce prescribing, purchases or recommendations, or include any payments of more than fair market value, may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, 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; • federal civil and criminal false claims laws, such as the civil False Claims Act (“ FCA ”), which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. For example, pharmaceutical companies have been prosecuted under the FCA in connection with, among other things their alleged off- label promotion of drugs, engaging in improper consulting arrangements with physicians, concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and providing free product to customers with the expectation that the customers would bill federal health care programs for the product. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “ any request or demand ” for money or property presented to the U. S. government. In addition, 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. Moreover, 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 FCA; • HIPAA which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third- party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry 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; • HIPAA, as amended by HITECH and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective business associates and covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U. S. federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions; • the federal transparency requirements under the Physician Payments Sunshine Act, created under the Affordable Care Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children’ s Health Insurance Program to report to CMS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician’ s immediate family members; • federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; • state and foreign law equivalents of each of the above federal laws, such as anti- kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non- governmental third- party payors, including private insurers; and • state and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry’ s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other health care providers; state and local laws that require the registration of pharmaceutical sales representatives; and state health information privacy laws, many of which differ from each other in significant ways and often are not pre- empted by HIPAA, thus requiring additional compliance efforts. We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of our product candidates, if approved, and have received equity awards as compensation for services provided to us. Because of the complex and far- reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may

influence the ordering of and use our product candidates, if approved, to be in violation of applicable laws. Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to significant investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource- consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Our current or future employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and applicable non- U. S. regulators, provide accurate information to the FDA and applicable non- U. S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, 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. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

Risks Related to Our Intellectual Property If we are unable to obtain and maintain sufficient intellectual property protection for Auxora, any future product candidates, and other proprietary technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize Auxora, any future product candidates, and other proprietary technologies if approved, may be adversely affected. Our commercial success will depend in part on our ability to obtain and maintain a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to Auxora, any future product candidates, and other proprietary technologies we develop. If we are unable to obtain or maintain patent protection with respect to Auxora, any future product candidates, and other proprietary technologies we may develop, our business, financial condition, results of operations, and prospects could be materially harmed. The patent position of biotechnology and pharmaceutical companies is highly uncertain and involves complex legal, scientific, and factual questions and has been the subject of frequent litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our patent applications may not result in patents being issued which protect Auxora, any future product candidates, and other proprietary technologies we may develop or which effectively prevent others from commercializing competitive technologies and products. Further, no consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently own or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting Auxora, any future product candidates, and other proprietary technologies and their uses by obtaining, defending and enforcing patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or may otherwise not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use and sell our potential product candidates;
- other parties may have designed

around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same composition of matter, methods or formulations or by claiming subject matter that could dominate our patent position; • any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products or product candidates that we may develop; • because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to Auxora, any future product candidates, and other proprietary technologies and their uses; • an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications for any application with an effective filing date before March 16, 2013; • there may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and • countries other than the United States may have patent laws less favorable to patentees than those upheld by U. S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates in those countries. The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, or maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. 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. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection for such output. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use Auxora, any future product candidates, and other proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. For example: • others may be able to make compounds that are similar to Auxora and any future product candidates but that are not covered by the claims of our patents; • we might not have been the first to make the inventions covered by our pending patent applications; • we might not have been the first to file patent applications for these inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies; • any patents that we obtain may not provide us with any competitive advantages; • we may not develop additional proprietary technologies that are patentable; • our competitors might conduct research and development activities in countries where we do not have patent rights or where patent protection is weak and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we cannot ensure that any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products; • we cannot ensure that we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own expire; or • the patents of others may have an adverse effect on our business. Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before U. S. or non- U. S. patent offices. We cannot be certain that the claims in our issued patents and pending patent applications covering Auxora or any future product candidates will be considered patentable by the USPTO, courts in the United States, or by patent offices and courts in foreign countries. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property internationally. The strength of patents in the biotechnology and pharmaceutical fields involves complex legal and scientific questions and can be uncertain. The patent applications that we own may fail to result in issued patents with claims that cover Auxora and any future product candidates in the United States or in foreign countries. Even if such patents do successfully issue, third parties may challenge the ownership, validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to our patents could deprive us of exclusive rights necessary for the successful commercialization of Auxora and any future product candidates. Furthermore, even if they are unchallenged, our patents may not adequately protect our intellectual property, provide exclusivity for Auxora or any future product candidates or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold with respect to Auxora or any future product candidates is threatened, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, Auxora or any future product candidates. For U. S. patent applications in which claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on

commercially reasonable terms. Our participation in an interference proceeding may fail and, even if successful, may result in substantial costs and distract our management and other employees. For U. S. patent applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law. In September 2011, the Leahy- Smith America Invents Act, or America Invents Act, was signed into law. The America Invents Act includes a number of significant changes to U. S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is developing regulations and procedures to govern the administration of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and in particular, the “ first to file ” provisions, were enacted on March 16, 2013. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. It remains unclear what impact the America Invents Act will have on the operation of our business. As such, the America Invents Act and its implementation could 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 have a material adverse effect on our business and financial condition. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non- provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we obtain patents covering our product candidates, when the terms of all patents covering a product expire, our business may become subject to competition from competitive products, including generic products. Given the amount of time required for the development, testing, and regulatory review and approval of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not obtain patent term extension for Auxora, our business may be materially harmed. Depending upon the timing, duration, and specifics of any FDA marketing approval of Auxora, or any future product candidate we may develop, one or more of patents issuing from our U. S. patent applications may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or (the “ Hatch- Waxman Amendments ”). The Hatch- Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate, or (“ SPC ”). If we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market Auxora and any future product candidates under patent protection would be reduced. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and / or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and / or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to foreign patent agencies. While an inadvertent lapse may sometimes 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. In such an event, our competitors might be able to enter the market with similar or identical products or technology earlier than should otherwise have been the case, which would have a material adverse effect on our business, financial condition, results of operations, and prospects. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect Auxora. As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Our patent rights may be affected by developments or uncertainty in U. S. or foreign patent statutes, patent case law, USPTO rules and regulations or the rules and regulations of foreign patent offices. Obtaining and enforcing patents in the biotechnology and pharmaceutical industry involve both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. In addition, the United States may, at any time, enact changes to U. S. patent law and regulations, including by legislation, by regulatory rule- making, or by judicial precedent, that adversely affect the scope of patent protection available and weaken the rights of patent owners to obtain patents, enforce patent infringement and obtain injunctions and / or damages. For example, the scope of patentable subject matter under 35 U. S. C. 101 has evolved significantly over the past several years as the Court of Appeals for the Federal Circuit and the Supreme Court issued various opinions, and the USPTO modified its guidance for practitioners on multiple occasions . **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. We cannot predict how decisions by the federal courts, the U. S. Congress or the USPTO may impact the value of our patent rights. For example, the Supreme Court of the United States held in Amgen v. Sanofi (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. In addition, the Federal circuit recently issued a decision, In re Collect, LLC (2023) involving the interaction of patent term adjustment (“PTA”), terminal disclaimers, and obvious- type double patenting which may affect the patent term of any issued patents that rely on any PTA. Other countries may likewise enact changes to their patent laws in ways that adversely diminish the scope of patent protection and weaken the rights of patent owners to obtain patents, enforce patent infringement, and obtain injunctions and / or damages. Further, the United States and other governments may, at any time, enact changes to law and regulation that create new avenues for challenging the validity of issued patents. For example, the America Invents Act created new administrative post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings that allow third parties to challenge the validity of issued patents. This applies to all of our U. S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. **In the 2013 case Assoc. for Molecular Pathology v. Myriad Genetics, Inc., for instance, the U. S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U. S. Congress or the USPTO may impact the value of our patents. For example, the Inflation Reduction Act (IRA) passed by Congress authorizes the Secretary of the Department of HHS to negotiate prices directly with participating manufacturers for selected medicines covered by Medicare even if these medicines are protected by an existing patent. For small molecule medicines, the process begins seven years after initial approval by the FDA. While we do not believe that the IRA or its effects will impact our ability to obtain patents in the near future, we cannot be certain whether it will affect our patent strategy in the long run.** We may not be able to protect our intellectual property rights throughout the world. Patents are of national or regional effect. Filing, prosecuting, and defending patents on Auxora, any future product candidates, and other proprietary technologies we develop in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights in the same manner and to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. 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 enforcement of such patent protection is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. The requirements for patentability may differ in certain countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval for a drug and its patent status. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. 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 biotechnology or pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In Europe, beginning June 1, 2023, European applications and patent may be subjected to the jurisdiction of the Unified Patent Court (“UPC”). Also, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty. As a single court system can invalidate a European patent, we, where applicable may opt out of the UPC and as such, each European patent would need to be challenged in each individual country. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, 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. ~~Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia’s invasion of Ukraine and the conflict in the Middle East may limit or prevent filing, prosecution and~~

~~maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. We currently maintain one granted patent in Russia.~~ We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees, collaborators or other third parties have an interest in our ~~patents-~~ **patent** rights, trade secrets, or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. For example, we may have inventorship disputes arise from conflicting views regarding the contributions of different individuals named as inventors, ~~the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent,~~ conflicting obligations of third parties involved in developing Auxora or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and / or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses. Our program may require the use of intellectual property rights held by third parties. The growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, Auxora may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license, on reasonable terms, proprietary rights related to any compositions, formulations, methods of use, processes or other intellectual property rights from third parties that we identify as being necessary for Auxora. Even if we are able to obtain a license to such proprietary rights, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Where we obtain licenses from or collaborate with third parties, 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 third parties, or such activities, if controlled by us, may require the input of such third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business, or in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such application. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, including making royalty and milestone payments, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business. Our business would suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical or similar to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability. The licensing and acquisition of third-party proprietary rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party proprietary rights that we may consider necessary or attractive in order to commercialize Auxora. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. For example, we may collaborate with U. S. and foreign academic institutions to accelerate our research development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate an exclusive license to any of the institution's proprietary rights in technology resulting from the collaboration. Regardless of such option to negotiate a license, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer, on an exclusive basis, their proprietary rights to other parties, potentially blocking our ability to pursue our program. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all. 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 successfully obtain rights to required third-party intellectual property rights on commercially reasonable terms, our ability to commercialize our products, and our business, financial condition, and prospects for growth, could suffer. Third-party claims alleging intellectual property infringement may prevent or delay our drug discovery and development efforts. Our success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including inter partes review, interference and reexamination proceedings before the USPTO, or oppositions and other comparable proceedings in foreign jurisdictions. The America Invents Act introduced new procedures including inter partes review and post grant review. The implementation of these procedures brings uncertainty to

the possibility of challenges to our patents in the future and the outcome of such challenges. 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 Auxora. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to Auxora may give rise to claims of infringement of the patent rights of others. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. We cannot assure you that any of our current or future product candidates will not infringe existing or future patents. We may not be aware of patents that have already issued that a third party might assert are infringed by one of our current or future product candidates. Nevertheless, we are not aware of any issued patents that will prevent us from marketing Auxora. Third parties may assert that we are employing their proprietary technology without authorization. There may be third- party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of Auxora. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending third- party patent applications which may later result in issued patents that Auxora, any future product candidates, and other proprietary technologies may infringe, or which such third parties claim are infringed by the use of our technologies. Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize Auxora or future product candidates. Defense of these claims, regardless of their merit, could involve substantial expenses and could be a substantial diversion of management and other employee resources from our business. If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties. Any claims of patent infringement asserted by third parties would be time- consuming and could:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing Auxora or any future product candidates until the asserted patent expires or is finally held invalid, unenforceable, or not infringed in a court of law;
- require us to develop non- infringing technology, which may not be possible on a cost- effective basis;
- require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property;
- require us to pay the attorney’ s fees and costs of litigation to the party whose intellectual property rights we may be found to be willfully infringing; and / or
- require us to enter into royalty or license agreements, which may not be available on commercially reasonable terms, or at all.

If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do either. Proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity before federal courts requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management’ s time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity or enforceability of the patents in court. Patent litigation is costly and time- consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non- infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing Auxora or any future product candidates to market and be precluded from developing, manufacturing or selling Auxora or any future product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. We cannot be certain that any of our patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived;
- pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, Auxora, and any future product candidates or the use of Auxora and any future product candidates;
- identification of third- party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims;
- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries

; and • additionally, generative artificial intelligence (AI) resources that are publicly available also present a risk that a company may inadvertently obtain, incorporate or use a third party’ s intellectual property. Furthermore, 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 and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. Further, we may incorrectly determine that our technologies, products, or product candidates are not covered by a third- party

patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or internationally that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or product candidates. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours, and others may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import Auxora and future approved products or impair our competitive position. Numerous third-party U. S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of Auxora. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U. S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U. S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications and may be entitled to priority over our applications in such jurisdictions. 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. If a third party prevails in a patent infringement lawsuit against us, we may have to stop making and selling the infringing product, pay substantial damages, including treble damages and attorneys' fees if we are found to be willfully infringing a third party's patents, 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 to obtain licenses from third parties to advance our research or allow commercialization of Auxora. 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 Auxora, which could harm our business significantly. Even if we were able to obtain a license, the rights may be nonexclusive, which may give our competitors access to the same intellectual property. We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. As is common in the biotechnology and pharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of Auxora, any future product candidates, and other proprietary technologies. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees. We may be involved in lawsuits to protect or enforce our patents which could be expensive, time-consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court, and we may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights. Third parties including competitors may infringe, misappropriate or otherwise violate our patents or patents that may issue to us in the future. To counter infringement or unauthorized use, we may need to or choose to file infringement claims, which can be expensive and time-consuming. We may not be able to prevent, infringement, misappropriation, or other violation of our intellectual property, particularly in countries where the laws may not protect those rights as fully as in the United States. If we choose to go to court to stop another party from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that such patents are invalid, unenforceable, or should not be enforced against that third party for any number of reasons. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements for patentability, including lack of novelty, obviousness, lack of written description, indefiniteness, or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution, i. e., committed inequitable conduct. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in foreign patent offices and courts and may result in the revocation, cancellation, or amendment of any foreign patents we hold now or in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents invalid. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference proceedings may fail and, even if

successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on 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 or manufacturing partnerships that would help us bring Auxora and any future product candidates to market. Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights 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, 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 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. 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. Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties. Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. We may rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors, and inventions agreements with employees, consultants, and advisors, to protect our trade secrets and other proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer, or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors, and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade

secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our future trademarks or trade names may be unable to be obtained, challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations. Moreover, any trade name we have proposed to use for products in the United States, such as Auxora must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. Similar requirements exist in Europe. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. **Any collaboration arrangements that we may enter..... resulting in civil or criminal proceedings.** General Risk Factors Our business operations may subject us to disputes, claims and lawsuits, which may be costly and time- consuming and could materially and adversely impact our financial position and results of operations. From time to time, we may become involved in disputes, claims and lawsuits relating to our business operations. In particular, we may face claims related to the safety of our products, intellectual property matters, employment matters, tax matters, commercial disputes, competition, sales and marketing practices, environmental matters, personal injury, insurance coverage and acquisition or divestiture- related matters. Any dispute, claim or lawsuit may divert management' s attention away from our business, we may incur significant expenses in addressing or defending any dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results. Litigation related to these disputes may be costly and time- consuming and could materially and adversely impact our financial position and results of operations if resolved against us. In addition, the uncertainty associated with litigation could lead to increased volatility in our stock price. 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, and the third parties with whom we share our facilities, 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 Each of our** operations involve the use of hazardous and flammable materials ~~, including chemicals and biological and radioactive materials. Each of our operations also~~ produce hazardous waste products. We generally contract with third parties for the disposal of these materials and waste. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, 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. These current or future laws and regulations may impair our research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Our business involves the use of hazardous materials and we and our third- party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business. Our research and development activities and our or any third- party manufacturers' and suppliers' activities involve the controlled

storage, use and disposal of hazardous materials owned by us. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers and suppliers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, this may not be the case or and we may not eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. Any contamination by such hazardous materials could therefore adversely affect our business, financial condition, results of operations and prospects. Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations. Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. 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. U. S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, including the U. S. Foreign Corrupt Practices Act (collectively, "Trade Laws"), prohibit, among other things, 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 over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and / or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. 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. The market price of our stock has been and may continue to be volatile, and you could lose all or part of your investment. The trading price of our common stock has been in the past, and may continue to be, highly volatile and subject to wide fluctuations in response to various factors, many of which we cannot control. Market prices for securities of early-stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include: • our ability to obtain regulatory approvals for product candidates, and delays or failures to obtain such approvals; • the failure of any of our product candidates, if approved for marketing and commercialization, to achieve commercial success; • any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices; • the entry into, or termination of, key agreements, including key licensing, supply or collaboration agreements; • the initiation of material developments in, or conclusion of, disputes or litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others; • changes in laws or regulations applicable to our product candidates; • the results of current, and any future, nonclinical or clinical trials of our product candidates; • announcements by commercial partners or competitors of new commercial products, clinical progress (or the lack thereof), significant contracts, commercial relationships, or capital commitments; • 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; • the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community; • adverse publicity relating to our markets, including with respect to other products and potential products in such markets; • the introduction of technological innovations or new therapies competing with our potential products; • announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors; • disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies; • the loss of key employees; • 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 an adverse or misleading opinion regarding our business and stock; • changes in the market valuations of similar companies; • general and industry-specific economic conditions potentially affecting our research and development expenditures; • sales of ~~its~~ **our** common stock by us or our stockholders in the future; • trading volume of our common stock; • changes in the structure of health care payment systems; • adverse regulatory decisions; • trading volume of our common stock; 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 or the biotechnology and pharmaceutical sectors, including as a result of disruptions to and volatility in the credit and financial markets

in the United States and worldwide from geopolitical and macroeconomic events, including the ongoing Russia- Ukraine and Middle East conflicts and related sanctions, and bank failures. These broad market fluctuations may also adversely affect the trading price 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 those companies. Regardless of the merits or the ultimate results of such litigation, if instituted, such litigation could result in substantial costs and diversion of management' s attention and resources, which could significantly harm our profitability and reputation. Financial reporting obligations of being a public company in the United States are expensive and time- consuming, and our management needs to devote substantial time to compliance matters. As a publicly traded company, we incur significant additional legal, accounting and other expenses that **CeleMedica the Company** did not incur as a privately held company, including costs associated with public company reporting requirements. The obligations of being a public company in the United States require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended (the " Exchange Act ") and the rules and regulations regarding corporate governance practices, including those under the Sarbanes- Oxley Act of 2002 (the " Sarbanes- Oxley Act "), the Dodd- Frank Wall Street Reform and Consumer Protection Act (the " Dodd- Frank Act ") and the listing requirements of the stock exchange on which our securities are listed. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain such insurance. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules and regulations will make some activities more time- consuming and costly, particularly after we are no longer an " emerging growth company " or a " small reporting company ". **We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering (i. e. December 31, 2025), (b) in which we have total annual gross revenue of at least \$ 1. 235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non- affiliates exceeds \$ 750 million as of the prior June 30th and (2) the date on which we have issued more than \$ 1. 0 billion in non- convertible debt during the prior three- year period. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation, among other potential problems.** Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation, among other potential problems. The relative lack of public company experience of our management team may put us at a competitive disadvantage. Our management team lacks significant public company experience, which could impair our ability to comply with legal and regulatory requirements such as, but not limited to, those imposed by the Sarbanes- Oxley Act. Our senior management does not have significant experience managing a publicly traded company. Such responsibilities include complying with federal securities laws and making required disclosures on a timely basis. Our senior management may be unable to implement programs and policies in an effective and timely manner or that adequately respond to the increased legal, regulatory and reporting requirements associated with being a publicly traded company. Our failure to comply with all applicable requirements could lead to the imposition of fines and penalties, distract our management from attending to the management and growth of our business, result in a loss of investor confidence in our financial reports and have an adverse effect on our business and stock price. Substantial future sales of shares of our common stock could adversely affect the market price of such shares. If existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, or there is the perception that these sales could occur, this could adversely affect the market price of such shares and could materially impair our ability to raise capital through equity offerings in the future. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale would have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, could adversely affect the market price of our common stock. Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. Based on the beneficial ownership of our common stock as of March 21, ~~2024~~ **2025**, our executive officers, directors and holders of 5 % or more of our capital stock and their respective affiliates beneficially owned a significant percentage of our voting stock. As a result, these stockholders, if continuing to act together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise. We are a smaller reporting company. We cannot be certain whether the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors or otherwise limit our ability to raise additional funds. We are a " smaller reporting company " under applicable securities regulations. A smaller reporting company is a company that, as of the last business day of its most recently completed fiscal quarter, has an aggregate market value of the company' s voting stock held by non- affiliates, or public float, of less than \$

250 million, or has annual revenues less than \$ 100 million and either no public float or public float less than \$ 750 million. SEC rules provide that companies with a non-affiliate public float of less than \$ 75 million may only sell shares under a Form S-3 shelf registration statement, during any 12-month period, in an amount less than or equal to one-third of the public float. If we do not meet this public float requirement, any offering by us under a Form S-3 will be limited to raising an aggregate of one-third of our public float in any 12-month period. In addition, a smaller reporting company is able to provide simplified executive compensation disclosures in its filings, is exempt from the provisions of Section 404 (b) of the Sarbanes-Oxley Act requiring that an independent registered public accounting firm provide an attestation report on the effectiveness of internal control over financial reporting if its public float is less than \$ 75-70 million, and has certain other reduced disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Reduced disclosure in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze its results of operations and financial prospects. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. 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 industry or equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock after the completion of the merger, 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 its stock price or trading volume to decline. Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management. Provisions in our amended and restated certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders, and the ability of the board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which prohibits stockholders owning in excess of 15 % of our voting stock from merging or combining with us in certain circumstances. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our Board of Directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing the members of management. Our 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 amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for any state law claims for (a) any derivative action or proceeding brought on behalf of us; (b) any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our directors, officers, stockholders, employees or agents to us or our stockholders; (c) any action asserting a claim against us or any of our directors, officers, stockholders, employees or agents arising pursuant to any provision of the DGCL, the certificate of incorporation or the bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; (d) any action to interpret, apply, enforce or determine the validity of the certificate of incorporation or the bylaws; or (e) any action asserting a claim against us or any of our directors, officers, stockholders, employees or agents governed by the internal affairs doctrine; provided, that these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. The amended and restated bylaws will provide that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The choice of forum provision may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and 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. If a court were to find the choice of forum provision contained in the bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our bylaws described above. 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. 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

or services. 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.