Risk Factors Comparison 2023-03-23 to 2022-03-08 Form: 10-K

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Investing in our common stock involves a high degree of risk. Investors should consider carefully the risks and uncertainties described below in addition to the other information included or incorporated by reference in this Annual Report on Form 10- K, as well as our other public filings with the Securities and Exchange Commission. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall. In addition to the risk factors identified under the captions below, the operation and results of our business are subject to risks and uncertainties identified elsewhere in this Annual Report on Form 10- K as well as general risks and uncertainties such as those relating to general economic conditions and demand in the market for our products. **An investment in our securities involves a high degree of risk. Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities.** Risks Related to Our Financial Condition and Need for Additional Capital ~~An investment in our securities involves a high degree of risk. Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities.~~ The COVID- 19 pandemic has adversely impacted, and may continue to adversely impact, our business, including the marketing, sale and commercialization of our products, our supply chain, our clinical trials, our liquidity and access to capital markets and our business development activities. **In addition, our business, financial condition and results of operations have been and may in the future be adversely affected by macroeconomic conditions and by geopolitical events.** The ~~ongoing~~ COVID- 19 pandemic has adversely impacted, and may continue to adversely impact, our business. In mid- March 2020, we implemented work- from- home policies which are still in place for the majority of our employees. Our work- from- home policies may negatively impact productivity or disrupt our business, the magnitude of which will continue to depend, in part, on the length of this continued remote working arrangement and other limitations on our ability to conduct our business in the ordinary course. During the second quarter of 2021, we developed and implemented plans to resume in- person work practices while adhering to relevant health authority guidance. The effects of government actions and our policies and those of third parties to reduce the spread and ameliorate the impact of COVID- 19 may negatively impact productivity and our ability to market and sell our products, cause disruptions to our supply chain and ongoing and future clinical trials and impair our ability to execute our business development strategy. These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition. The marketing, sale and commercialization of our products have **previously** been ~~adversely impacted and may continue to be~~ adversely impacted by COVID- 19 and actions taken to slow its spread and ameliorate its impact. ~~We~~ **For example, in 2020 we** saw a variable impact on our product revenues in 2020 due to the COVID- 19 pandemic and also experienced variable impacts on our business and financial condition as a result ~~of the pandemic. We are expecting the impact on our near- term financial results to continue for the duration~~ of the pandemic. Other parts of our business have been, and continue to be, impacted by the outbreak. For example, patients have postponed and we expect will continue to postpone visits to healthcare provider facilities, certain healthcare providers have temporarily closed their offices or are restricting patient visits, healthcare provider employees may become generally unavailable and there could be disruptions in the operations of payors, distributors, logistics providers and other third parties that are necessary for our products to be prescribed, reimbursed and administered to patients. For example, we have continued to observe a reduction in the number of Bendeka patients visiting infusion centers, hospitals and clinics for intravenous administration of Bendeka due to interruptions in healthcare services, and the patients' inability to visit administration sites and desire to avoid contact with infected individuals. In addition, our sales and marketing teams have been working remotely and our virtual initiatives with respect to marketing and supporting the sale and administration of our products have not been as effective as our in- person sales and marketing activities. We cannot predict when we will be able to resume in- person sales and marketing activities. Quarantines, shelter- in- place, safer- at- home and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could be re- implemented or could continue to occur, related to COVID- 19 or other infectious diseases could impact personnel at third- party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our products. In particular, some of our suppliers of certain materials used in the production of our drug products are located in regions that continue to be subject to COVID- 19- related actions and policies that limit the conduct of normal business operations. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to the COVID- 19 pandemic, our ability to continue meeting commercial demand for our products in the United States or advancing development of our product candidates may become impaired. ~~At this time, we consider our inventories on hand to be sufficient to meet our commercial requirements.~~ In addition, our clinical trials ~~have been~~ **may be** affected by ~~COVID- 19~~ **epidemics, pandemics or other disruptions** . **For example, from 2020 to 2022,** ~~Clinical~~ **clinical** site initiation and patient enrollment **was** ~~has been~~ delayed due to prioritization of hospital resources toward COVID- 19. **As** ~~Current or potential patients in our ongoing or planned clinical trials have chosen to not enroll, not participate in follow- up clinical visits or drop out of the trial as~~ a **result** ~~precaution against contracting COVID- 19. Further, some patients may not be able to comply with clinical trial protocols if quarantines continue to impede patient movement or interrupt healthcare services. Some clinical sites in the United States have slowed or stopped further enrollment of new patients in clinical trials, denied access to site monitors or otherwise curtailed certain operations. For example~~ , the clinical trial timelines for certain of our product candidates, including EA- 114 (our fulvestrant product candidate),

have been delayed given difficulties with patient enrollment resulting from the COVID- 19 pandemic, and we expect that clinical trial timelines will continue to be delayed for the duration of the pandemic. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID- 19, has been and may continue to be adversely impacted. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials. The **extent** ~~spread of COVID- 19 and actions taken~~ to **which consequences** ~~reduce its spread and ameliorate its impact may also materially affect us economically. As a result~~ of the COVID- 19 pandemic **continue** ~~and actions taken~~ to ~~slow its spread and ameliorate its~~ impact **the marketing** , **sale and commercialization of our products, our supply chain, our clinical trials, our access to capital and our business development activities continues to be uncertain, including with respect to negative impacts on the economy and capital markets. In addition, our financial condition, results of operations, business and cash flow may be negatively affected by general economic, industry and market conditions in** the global ~~credit~~ **economy** and **in the global** financial markets ~~have experienced extreme volatility~~ **, such as rising inflation** and **interest rates, increased costs of goods, supply chain** disruptions ~~, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates~~ and uncertainty about economic stability **and the financial markets. The global economy has experienced extreme volatility and disruptions from international conflicts, terrorism or other geopolitical events, such as the ongoing conflict between Russian and Ukraine, and related sanctions and other economic disruptions or concerns. On February 24, 2022, Russia initiated significant military action against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions if the conflict continues or worsens. It is not possible to predict the broader consequences of the conflict, including related geo- political tensions, and the measures and retaliatory actions that will be taken by the United States and other countries in respect thereof, as well as any countermeasures or retaliatory actions Russia may take in response, are likely to cause regional instability and geo-political shifts and could materially adversely affect global trade, currency exchange rates, regional economies, and the global economy. Additional actions that we or others may take in response to the conflict could increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our products or products or our partners 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** . If the equity and credit markets deteriorate, it may make any ~~additional~~ **necessary** debt or equity financing more difficult, more costly ~~or~~ **, and** more dilutive. ~~While~~ **Failure to secure any necessary financing in a timely manner and on favorable terms could impair our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon our plans and programs. In addition,** ~~the~~ **there** ~~potential~~ **is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult** economic **times** ~~impact brought by, and the duration of, the COVID- 19 pandemic may be difficult to assess or predict, there could continue to be a significant disruption of global financial markets, reducing our ability to access capital~~ , which could ~~negatively~~ **directly** affect our ~~liquidity~~ **ability to attain our operating goals on schedule and on budget. We cannot anticipate all of the ways in which the current economic climate** and financial ~~position or~~ **market conditions could adversely impact** our business ~~development activities~~ . **If we** ~~The COVID- 19 pandemic continues to rapidly evolve. The extent to which COVID- 19 continues to impact the marketing, sale and commercialization of our products, our supply chain, our clinical trials, our access to capital and our business development activities, depends on future developments, which are highly uncertain and~~ cannot ~~be predicted with confidence, such as the ultimate geographic spread of the pandemic, the duration of the pandemic and the efforts by governments and business to contain it, business closures or business disruptions, any re- opening plans, additional closures and spikes or surges in COVID- 19 infection, and the impact on the economy and capital markets. If we cannot achieve or~~ sustain profitability, our business, prospects, operating results and financial condition would be materially harmed. We have focused primarily on developing a broad product portfolio and currently have final regulatory approval for a limited number of products. Some of our product candidates will require substantial additional development time and resources before we would be able to receive regulatory approvals, implement commercialization strategies and begin generating revenue from product sales. We had net ~~loss~~ **income** of $ ~~8~~ **35** . 6 million for the year ended December 31, ~~2021~~ **2022** , and net ~~income~~ **loss** of $ ~~12~~ **8** . ~~0~~ **6** million for the year ended December 31, ~~2020~~ **2021** , **and net income of** $ ~~14~~ **12** . ~~3~~ **0** million for the year ended December 31, **2020** ~~2019, and $ 31. 9 million for the year ended December 31, 2018~~ , respectively ~~, and we incurred significant net losses prior to 2015~~ . We have devoted most of our financial resources to product development and may not generate significant revenue from sales of our product candidates in the near- term, if ever. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to fully predict the timing or amount of our expenses, but we expect to continue to incur substantial expenses, which we expect to increase as we expand our development activities and product portfolio. As a result of the foregoing, we may incur losses and negative cash flows in the future. If we fail to obtain additional financing, we could be forced to delay, reduce or eliminate our product development programs. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs, both internally and through our external joint development agreements. Changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our product commercialization or development efforts could encounter technical or other difficulties that could increase our development costs more than we expect. In any event, we may require

additional capital prior to obtaining regulatory approval for, or commercializing, any additional product candidates. In addition, attempting to secure additional financing may divert our management from our day- to- day activities, which may adversely affect our ability to develop and commercialize additional product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to: • significantly delay, scale back or discontinue the development or commercialization of our product candidates; • seek corporate partners for our products and product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; • relinquish or license on unfavorable terms, our rights to technologies or products, or to product candidates that we otherwise would seek to develop or commercialize ourselves; or • significantly curtail, or cease, operations. The occurrence of any of these factors could have a material adverse effect on our business, operating results and prospects. We may sell additional equity or incur debt to fund our operations, which may result in dilution to our stockholders and impose restrictions on our business. In order to raise additional funds to support our operations, we may sell additional equity or incur debt, which could adversely impact our stockholders, as well as our business. The sale of additional equity or convertible debt securities would result in the issuance of additional shares of our capital stock and dilution to all of our stockholders. The incurrence of indebtedness results in increased fixed payment obligations. In addition, the incurrence of indebtedness also results in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. On November ~~8~~ **1** , ~~2019~~ **2022** , we entered into the ~~Second~~ **Third** Amended and Restated Credit Agreement, or the ~~Revised~~ **Third Amended** Credit Agreement, with JPMorgan Chase Bank, N. A., as administrative agent, and the lenders party thereto, which replaced our prior credit agreement. The terms and amounts borrowed under the ~~Revised~~ **Third Amended** Credit Agreement includes a drawn term loan of $ ~~40~~ **50** million and **a** ~~an undrawn~~ revolving credit facility of $ ~~110~~ **100** million **,** ~~. The schedule~~ of ~~principal payments~~ **which $ 15. 0 million was drawn on November 1, 2022. All amounts outstanding under the Third Amended Credit Agreement shall be due and payable on October 31, 2025, unless otherwise accelerated** ~~for~~ **or** ~~the new term loan facility has been~~ extended ~~until November 8, 2022~~ **pursuant to the terms of the Third Amended Credit Agreement** . We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay our indebtedness at the time any such repayment is required (causing a default under such indebtedness), which could have a material adverse effect on our business, financial condition and results of operations. 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 and use or other tax laws or regulations could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws and regulations could be interpreted, modified or applied adversely to us. These events could require us to pay additional taxes on a prospective or retroactive basis, as well as penalties, interest and other costs for past amounts deemed to be due. New laws, or laws that are changed, modified or newly interpreted or applied, also could increase our compliance, operating and other costs, as well as the costs of our products. For example, **recent legislation in the United States, commonly referred to as the Inflation Reduction Act, enacts a minimum tax equal to 15 percent of the adjusted financial statement income of certain large U. S. corporations for tax years beginning after December 31, 2022, as well as a one percent excise tax on stock repurchases imposed on public corporations making such repurchases after December 31, 2022. Further,** the Tax Act enacted many significant changes to the U. S. tax laws, some of which were further modified by the Coronavirus Aid, Relief, and Economic Security Act, and may be modified in the future by the current or a future presidential administration **. Among other changes, the Tax Act amended the Code to require that certain research and experimental expenditures be capitalized and amortized over five years if incurred in the United States or fifteen years if incurred in foreign jurisdictions for tax years beginning after December 31, 2021. Although the U. S. Congress has considered legislation that would defer, modify, or repeal the capitalization and amortization requirement, there is no assurance that such changes will be made. If the requirement is not deferred, repealed or otherwise modified, it may increase our cash taxes and effective tax rate** . In addition, it is uncertain if and to what extent various states will conform to current federal law, or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net operating losses, and other deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets and could increase our future tax expense. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020, is limited to 80 % of taxable income. It is uncertain if and to what extent various states will conform to federal law. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an" ownership change," generally defined as a greater than 50 % change (by value) in its equity ownership over a three year period, the corporation' s ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes, such as research tax credits, to offset its post- change income or taxes may be limited. In addition, 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 net operating loss carryforwards 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 net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Risks Related to Regulatory Approval We cannot give any assurance that we will receive regulatory approval for our product candidates, which is necessary before they can be commercialized. Our business and future success are substantially dependent on our or our collaborators' ability to successfully and timely develop, obtain regulatory approval for, and commercialize our product candidates. Any delay or setback in the development of any of

these product candidates could adversely affect our business. For example, on August 7, 2020, we received a CRL for our NDA for Ryanodex for the treatment of EHS. We decided that we will no longer pursue this indication in order to direct our resources to other product candidates. In addition, on January 26, 2022, Tyme announced the discontinuation of SM- 88 with methoxsalen, phenytoin, and sirolimus in a trial for metastatic pancreatic cancer. Our planned development, approval and commercialization of any product candidates may fail to be completed in a timely manner or at all. The FDA or other foreign regulatory agency may refuse or delay approval of our product candidates for failure to collect sufficient clinical or animal safety data and require us or our collaborators to conduct additional clinical or animal safety studies, which may cause lengthy delays and increased costs to our programs. We cannot provide assurance that we will be able to obtain approval for any of our product candidates from the FDA or any foreign regulatory authority or that we will obtain such approval in a timely manner. If we do not obtain regulatory approval of new products or additional indications for existing products, or are significantly delayed or limited in doing so, our revenue growth will be adversely affected, we may experience surplus inventory, or our business may be materially harmed and we may need to significantly curtail operations. If we are unable to differentiate our products or product candidates from branded reference drugs or existing generic therapies for similar treatments, or if the FDA or other applicable regulatory authorities approve generic products that compete with any of our products or product candidates, the ability to successfully commercialize our product candidates would be adversely affected. Our strategy is to enter the market no later than the first generic to the applicable branded reference drug. We expect to compete against branded reference drugs and to compete with their generic counterparts that will be sold for a lower price. Although we believe that our products and product candidates will be clinically differentiated from branded reference drugs and their generic counterparts, if any, it is possible that such differentiation will not impact our market position. If we are unable to achieve significant differentiation for our products or product candidates against other drugs, the opportunity for our products and product candidates to achieve premium pricing and be commercialized successfully would be adversely affected. In addition to existing branded reference drugs and the related generic products, the FDA or other applicable regulatory authorities may approve generic products that compete directly with our products or product candidates, if approved. Once an NDA, including a 505 (b) (2) application, is approved, the product covered thereby becomes a" listed drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA. The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non- infringing versions of a drug to facilitate the approval of an ANDA for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient (s), dosage form, strength, route of administration and conditions of use or labeling as our products or product candidates and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our products or product candidates. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents of our products or product candidates would materially adversely impact our ability to successfully commercialize our product candidates or negatively impact our ability to gain market acceptance and market share for our products. If the FDA does not conclude that our product candidates satisfy the requirements for the regulatory approval, or if the requirements for approval of any of our product candidates are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful. We intend to seek FDA approval through the 505 (b) (2) regulatory pathway for those small molecule product candidates described in this Annual Report on Form 10- K. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch- Waxman Act, added Section 505 (b) (2) to the FDCA. Section 505 (b) (2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant. If the FDA does not allow us to pursue the regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue such regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue our chosen regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate. In addition, we expect that our competitors will file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit. Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development. Clinical testing, even when utilizing the 505 (b) (2) pathway or its equivalent, is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as safe and effective. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our product candidates are in various stages of development, from early stage to late stage. Clinical trial failures may occur at any stage and may result from a multitude of factors both within and outside our control, including flaws in formulation, adverse safety or efficacy profile and flaws in trial design, among others. If the trials result in negative or inconclusive results, we or our collaborators may decide, or regulators may require us, to discontinue trials of the product candidates or conduct additional

clinical trials or preclinical studies. **For example, on January 26, 2022, our collaboration partner Tyme announced the discontinuation of the Phase 2 clinical trial of SM- 88 with methoxsalen, phenytoin, and sirolimus in patients with metastatic pancreatic cancer.** In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. For these reasons, our future clinical trials may not be successful. We do not know whether any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If any product candidate for which we are conducting clinical trials is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it. If we are unable to bring any of our current or future product candidates to market, our business would be materially harmed and our ability to create long- term stockholder value will be limited. Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and could jeopardize or delay our ability to obtain regulatory approval and commence product sales. We may also find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our product candidates. We may experience delays in clinical trials of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including: • inability to raise or delays in raising funding necessary to initiate or continue a trial; • delays in obtaining regulatory approval to commence a trial; • delays in reaching agreement with the FDA on final trial design; • imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities; • delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, or failure by such CROs to carry out the clinical trial at each site in accordance with the terms of our agreements with them; • delays in obtaining required institutional review board, or IRB, approval at each site; • difficulties or delays in having patients complete participation in a trial or return for post- treatment follow- up; • clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment; • delays related to the COVID- 19 pandemic **or other health epidemics** , which may result in clinical site closures, delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols; • time required to add new clinical sites; or • delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials. If initiation or completion of our planned clinical trials is delayed for any of the above reasons or other reasons, our development costs may increase, our regulatory approval process could be delayed and our ability to commercialize and commence sales of our product candidates could be materially harmed, which could have a material adverse effect on our business. In addition, identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow- up periods. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics or to complete our clinical trials in a timely manner. Patient enrollment and completion of the trials is affected by factors including: • severity of the disease under investigation; • design of the trial protocol; • size of the patient population; • eligibility criteria for the trial in question; • perceived risks and benefits of the product candidate under trial; • proximity and availability of clinical trial sites for prospective patients; • availability of competing therapies and clinical trials; • efforts to facilitate timely enrollment in clinical trials; • patient referral practices of physicians; and • ability to monitor patients adequately during and after treatment. Our products or product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance, or result in significant negative consequences following marketing approval, if any. As with many pharmaceutical and biological products, treatment with our products or product candidates may produce undesirable side effects or adverse reactions or events. Although our products or product candidates containing active ingredients that have already been approved and the side effects arising from the use of the active ingredient or class of drug in our products or product candidates are generally known, our products or product candidates may still cause undesirable side effects. These could be attributed to the active ingredient or class of drug or to our unique formulation of such products or product candidates, or other potentially harmful characteristics. Such characteristics could cause us, our IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly. Further, if any of our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution; • the FDA may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS; • regulatory authorities may require the addition of labeling statements, such as warnings or contraindications; • we may be required to change the way the product is administered or conduct additional clinical studies; • we could be sued and held liable for harm caused to patients; or • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or product candidate and could substantially increase the costs of commercializing our products and product candidates. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time- consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. To date, we have obtained regulatory approval for five NDA products, but no BLA products, and we have multiple NDA product candidates in advanced stages of development and other exploratory candidates under development. However, it is possible that none of our existing product candidates or any product candidates we may seek to develop in the

future will ever obtain regulatory approval in the United States or other jurisdictions. Our product candidates could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree that our changes to branded reference drugs or existing biologic drugs meet the criteria for our chosen regulatory pathway or foreign regulatory pathways; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective or comparable to its branded reference product for its proposed indication; • the results of any clinical trials we conduct may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; • the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval. This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would harm our business, results of operations and prospects significantly. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post- marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates. We have limited experience using the 505 (b) (2) regulatory pathway to submit an NDA or any similar drug approval filing to the FDA, and we cannot be certain that any of our product candidates will receive regulatory approval. There can be no assurance that the FDA will ultimately approve any submitted NDA by us in a timely fashion. For example, in March of 2016 we received a CRL from the FDA with respect to our NDA for EP- 6101, and we elected not to pursue the application further or seek to exploit EP- 6101 for various reasons. On August 7, 2020, we received a CRL for our NDA for Ryanodex for the treatment of EHS, and we decided that we will no longer pursue this indication in order to direct our resources to other product candidates. The failure to receive regulatory approvals for our product candidates could have a material adverse effect on our business, financial condition and operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved. An NDA submitted under Section 505 (b) (2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidates. Some of our product candidates will be submitted to the FDA for approval under Section 505 (b) (2) of the FDCA. Section 505 (b) (2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by, or for, the applicant and on which the applicant has not obtained a right of reference. The 505 (b) (2) application would enable us to reference published literature and / or the FDA' s previous findings of safety and effectiveness for the branded reference drug. For NDAs submitted under Section 505 (b) (2) of the FDCA, the patent certification and related provisions of the Hatch- Waxman Act apply. In accordance with the Hatch- Waxman Act, such NDAs may be required to include certifications, known as paragraph IV certifications, that certify that any patents listed in the Patent and Exclusivity Information Addendum of the FDA' s publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, with respect to any product referenced in the 505 (b) (2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505 (b) (2) NDA. Under the Hatch- Waxman Act, the holder of patents that the 505 (b) (2) application references may file a patent infringement lawsuit after receiving notice of the paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505 (b) (2) applicant within 45 days of the patent owner' s receipt of notice triggers a one- time, automatic, 30- month stay of the FDA' s ability to approve the 505 (b) (2) NDA, unless patent litigation is resolved in the favor of the paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. For example, we have been, and may in the future be, subject to litigation brought in connection with our filing of a 505 (b) (2) NDA. In addition, a 505 (b) (2) application will not be approved until any non- patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, or NCE, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the branded reference drug, which could be time- consuming and could substantially delay our achievement of regulatory approvals for such product candidates. The FDA may also reject our future 505 (b) (2) submissions and require us to file such submissions under Section 505 (b) (1) of the FDCA, which would require us to provide extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and be considerably more expensive and time- consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates. Companies that produce branded reference drugs routinely bring litigation against abbreviated new drug application, or ANDA, or 505 (b) (2) applicants that seek regulatory approval to manufacture and market generic and reformulated forms of their branded products. These companies often allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an ANDA or 505 (b) (2) applicant. For example, we were involved in a patent case with ~~Par~~ **a subsidiary of Endo** related to our ANDA for vasopressin. Likewise, patent holders may bring patent infringement suits against companies that are currently marketing and selling their approved generic or reformulated products. Litigation to enforce or defend intellectual property rights is often complex and often involves significant expense and can delay or prevent introduction or sale of our product candidates. If patents are held to be valid and infringed by our product candidates in a particular jurisdiction, we would, unless we could obtain a license from the patent holder, be

required to cease selling in that jurisdiction and may need to relinquish or destroy existing stock in that jurisdiction. There may also be situations where we use our business judgment and decide to market and sell our approved products, notwithstanding the fact that allegations of patent infringement (s) have not been finally resolved by the courts, which is known as an" at- risk launch." The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. Moreover, because of the discount pricing typically involved with bioequivalent and, to a lesser extent, 505 (b) (2), products, patented branded products generally realize a substantially higher profit margin than bioequivalent and, to a lesser extent, 505 (b) (2), products, resulting in disproportionate damages compared to any profits earned by the infringer. An adverse decision in patent litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. If we are found to have improperly promoted off- label uses of our products or product candidates, if approved, we may become subject to significant liability. Such enforcement has become more common in the industry. 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. However, we may share truthful and not misleading information that is otherwise consistent with our products' FDA approved labeling. If we receive marketing approval for our product candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment it could be used in such manner. However, if we are found to have promoted our products for any off- label uses, the federal government could levy civil, criminal and administrative penalties, and seek fines against us. The FDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. Our business is subject to extensive regulatory requirements and our approved product and product candidates that obtain regulatory approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products. Even after a product is approved, we remain subject to ongoing FDA and other regulatory requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record- keeping and reporting of safety and other post- market information. The holder of an approved NDA is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the application. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product' s approval may contain requirements for potentially costly post- approval studies and surveillance to monitor the safety and efficacy of the product, or the imposition of a REMS program. Manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and adherence to commitments made in the drug application. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing. If we or our products or product candidates or our manufacturing facilities fail to comply with applicable regulatory requirements, a regulatory agency may: • issue warning letters or untitled letters asserting that we are in violation of the law; • impose restrictions on the marketing or manufacturing of the product; • seek an injunction or impose civil, criminal and / or administrative penalties, damages, assess monetary fines, require disgorgement, consider exclusion from participation in Medicare, Medicaid and other federal health care programs and require curtailment or restructuring of our operations; • suspend or withdraw regulatory approval; • suspend any ongoing clinical trials; • refuse to approve a pending application or supplements to an application submitted by us; • seize product; or • refuse to allow us to enter into government contracts. Similar post- market requirements may apply in foreign jurisdictions in which we may seek approval of our products. 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 ability to commercialize our products and generate revenues. In addition, the FDA' s regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post- approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products and / or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability. Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors 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 that our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional,

reckless and / or negligent conduct that violates (1) the laws of the FDA and similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulatory bodies; (2) health care laws and regulations, including fraud and abuse laws of the United States and similar foreign fraudulent misconduct laws; and (3) laws requiring the reporting of financial information or data accurately. Specifically, the promotion, sales and marketing of health care items and services, as well as certain business arrangements in the health care industry are subject to extensive laws designed to prevent misconduct, including fraud, kickbacks, self- dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing, structuring and commission (s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. It is not always possible to identify and deter employee and other third- party misconduct. The precautions we take to detect and prevent inappropriate conduct 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. If any such actions are instituted against us, and we are not successful in defending ourselves, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Any relationships with health care professionals, principal investigators, consultants, customers (actual and potential) and third party payors, in addition to our general business operations, are and will continue to be subject, directly or indirectly, to federal and state health care fraud and abuse laws, marketing expenditure tracking and disclosure, or sunshine laws, government price reporting and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations. Our business operations and activities may be directly, or indirectly, subject to various federal, state and local fraud and abuse laws, including, without limitation, the federal Anti- Kickback Statute and the federal civil False Claims Act. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as current, proposed and future sales, marketing and education programs. In addition, we may be subject to patient data privacy and security regulation by the federal government, state governments and foreign jurisdictions in which we conduct our business, as well as transparency requirements. The U. S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal health care program, such as the Medicare and Medicaid programs. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, among other things, amends the intent requirement of the federal Anti- Kickback Statute and criminal healthcare fraud statutes such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act; • federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalty laws, which prohibit and impose penalties for, among other things, individuals or entities knowingly presenting, or causing to be presented, claims for payment or approval from the federal government including Medicare, Medicaid or certain other governmental health care programs that are false or fraudulent or knowingly making or causing to be made a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government; • the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal civil and criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, regardless of the payor (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, health care benefits, items or services relating to health care matters; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain health care providers, health plans and health care clearinghouses, known as covered entities, or business associates, as well as their respective business associates, independent contractors or agents of covered entities that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization; • the federal Physician Payments Sunshine Act, created under Section 6002 of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services' Centers for Medicare & Medicare Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants an nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members; • federal consumer

protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; • federal government price reporting laws, changed by ACA to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and / or discounts on our marketed drugs. Participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs and potentially limit our ability to offer certain marketplace discounts; • the Foreign Corrupt Practices Act, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and • state law equivalents of each of the above federal laws, such as anti- kickback, false claims, consumer protection and unfair competition laws which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving health care items or services reimbursed by any third party payors, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to health care providers; state laws that require drug manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to health care professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and / or increase enforcement scrutiny of our activities), and drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts. In addition, any sales of our products or product candidates once commercialized outside the United States will also likely subject us to foreign equivalents of the health care laws mentioned above, among other foreign laws. Efforts to ensure that our business arrangements will comply with applicable health care laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate. We are required to obtain regulatory approval for each of our products in each jurisdiction in which we intend to market such products, and the inability to obtain such approvals would limit our ability to realize their full market potential. In order to market products outside of the United States, we must 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. However, the failure to obtain regulatory approval in one jurisdiction may adversely impact our ability to obtain regulatory approval in another jurisdiction. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non- clinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed. If we fail to develop, acquire or in- license other product candidates or products, our business and prospects will be limited. Our long- term growth strategy is to develop and commercialize a portfolio of product candidates in addition to our existing product candidates. We may also acquire or in- license such product candidates, such as the license agreements we entered into with Combioxin for CAL02 and with AOP Orphan for Landiolol **and our acquisition of the rights to BARHEMSYS and BYFAVO** . Although we have internal research and development capacity that we believe will enable us to make improvements to existing compounds or active ingredients, we do not have internal drug discovery capabilities to identify and develop entirely new chemical entities or compounds. As a result, our primary means of expanding our pipeline of product candidates is to develop improved formulations and delivery methods for existing FDA- approved products and / or select and acquire or in- license product candidates for the treatment of therapeutic indications that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Developing new formulations of existing products or identifying, selecting and acquiring or in- licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual development, acquisition or in- license of a particular product candidate, potentially resulting in a diversion of our management' s time and the expenditure of our resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long- term business and prospects will be limited. Risks Related to Commercialization of Our Products and Product Candidates Our commercial success depends upon attaining significant market acceptance of our products and product candidates, if approved, among physicians, nurses, pharmacists, patients and the medical community. Even if we obtain regulatory approval for our product candidates, our products and product candidates may not gain market acceptance among physicians, nurses, pharmacists, patients, the medical community or third party payors, which is critical to commercial success. Market acceptance of our products and any product candidate for which we receive approval depends on a number of factors, including: • the timing of market introduction of the

product candidate as well as competitive products; • the clinical indications for which the product candidate is approved; • the convenience and ease of administration to patients of the product candidate; • the potential and perceived advantages of such product candidate over alternative treatments; • the cost of treatment in relation to alternative treatments, including any similar generic treatments; • the availability of coverage and adequate reimbursement by third party payors and government authorities; • relative convenience and ease of administration; • any negative publicity related to our or our competitors' products that include the same active ingredient; • the prevalence and severity of adverse side effects, including limitations or warnings contained in a product' s FDA- approved labeling; and • the effectiveness of sales and marketing efforts. Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. If our products or product candidates, if approved, fail to achieve an adequate level of acceptance by physicians, nurses, pharmacists, patients and the medical community, we will be unable to generate significant revenues, and we may not become or remain profitable. **For example, in the first quarter of 2023 we decided to exit the vasopressin market by discontinuing all related manufacturing and halting sales beyond current inventory levels that are expected to be depleted by the end of the second quarter of 2023.** Guidelines and recommendations published by government agencies can reduce the use of our products and product candidates. Government agencies promulgate regulations and guidelines applicable to certain drug classes which may include our products and product candidates that we are developing. Recommendations of government agencies may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Regulations or guidelines suggesting the reduced use of certain drug classes which may include our products and product candidates that we are developing or the use of competitive or alternative products as the standard of care to be followed by patients and health care providers could result in decreased use of our product candidates or negatively impact our ability to gain market acceptance and market share. If we are unable to successfully conduct our sales and marketing capabilities or if our commercial partners do not adequately perform, the commercial opportunity for our products may be diminished. We have a commercial organization to promote certain of our approved products in the United States. The cost of maintaining such an organization may exceed the benefits, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. In addition, we may not be successful in commercializing our products despite such commercial organization. We and any other commercialization partner we engage in the future may not be able to attract, hire, train and retain qualified sales and sales management personnel. If we or our future partners, if any, are not successful in maintaining an effective number of qualified sales personnel, our ability to effectively market and promote our products may be impaired. The efforts of our partners in many instances would likely be outside our control. If any future partner is unsuccessful in their efforts, or we are unable to maintain such commercial partnerships or to effectively establish alternative arrangements for our products, our business could be adversely affected. A substantial portion of our total revenues is derived from sales of a limited number of products. We derive a substantial portion of our revenue from royalties derived from the sales of one product: Bendeka. This product is sold by our partner Teva Pharmaceuticals. During the year ended December 31, ~~2021~~ **2022** , Bendeka accounted for approximately ~~66~~ **33** % of our total revenue. The sale of our products can be significantly influenced by the efforts of our partners, which are out of our control, as well as market conditions and regulatory actions. We may experience decreases in the sale of our products in the future as a result of actions taken by our competitors, such as price reductions or entry into the market for competing products, or as a result of regulatory actions related to our products or competing products, which could have a material impact on our results of operations and financial condition. If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business. We may enter into agreements with third parties to market our products outside the United States. We expect that we will be subject to additional risks related to entering into international business relationships, including: • different regulatory requirements for drug approvals in foreign countries; • differing payor reimbursement regimes, governmental payors or patient self- pay systems and price controls; • reduced protection for intellectual property rights; • unexpected changes in tariffs, trade barriers and regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign taxes, including withholding of payroll taxes; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; • workforce uncertainty in countries where labor unrest is more common than in the United States; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires or public health issues or pandemics including the coronavirus. We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Many of our competitors both in the United States and internationally, include major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, Ryanodex, and products with dantrolene sodium as the API, is currently marketed in the United States by, among others, Endo International plc, Impax Laboratories, Inc., Hikma Pharmaceuticals, LLC, US WorldMeds, LLC, Mylan Institutional, LLC, and Elite Laboratories, Inc. While our formulations of this product is distinct, and we believe improvements, compared to those competitors mentioned, competition from these products on factors such as price and availability effect our commercial efforts. Additionally, we must compete with alternative drug treatments (as opposed to alternative formulations) for many of the indications that our products are approved to treat. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology

and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than our products or any product candidate that we are currently developing or that we may develop. In addition, our competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that our products, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any application we submit. We believe that our ability to successfully compete will depend on, among other things: • the efficacy and safety of our products and product candidates, including as relative to marketed products and product candidates in development by third parties; • the time it takes for our product candidates to complete clinical development and receive marketing approval; • the ability to maintain a good relationship with regulatory authorities; • the ability to commercialize and market any of our product candidates that receive regulatory approval; • the price of our products, including in comparison to branded or generic competitors; • whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare; • the ability to protect intellectual property rights related to our products and product candidates; • the ability to manufacture on a cost- effective basis and sell commercial quantities of our products and product candidates that receive regulatory approval; and • acceptance of any of our products and product candidates that receive regulatory approval by physicians and other health care providers. If our competitors market products that are more effective, safer or less expensive than our products or product candidates, or that reach the market sooner than our product candidates, we may enter the market too late in the cycle and may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies, products or product candidates obsolete, less competitive or not economical. We could incur substantial costs and disruption to our business and delays in the launch of our product candidates if our competitors and / or collaborators bring legal actions against us, which could harm our business and operating results. We cannot predict whether our competitors or potential competitors, some of whom we collaborate with, may bring legal actions against us based on our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, claiming, among other things, infringement of their intellectual property rights, breach of contract or other legal theories. **For example, in the first quarter of 2023, Curia Global, Inc. (“ Curia ”) filed a demand for arbitration against us for breach of contract, account stated and breach of the implied covenant of good faith and fair dealing arising from our supply agreement with Curia relating to vasopressin, seeking damages in excess of $ 76. 7 million. In addition, Curia filed an action against us in New York State Court, claiming breach of contract and account stated arising from our supply agreement with Curia relating to PEMFEXY, seeking damages in excess of $ 4. 2 million. We cannot assure we will be successful in defending such claims.** If we are forced to defend any such lawsuits, whether they are with or without merit or are ultimately determined in our favor, we may face costly litigation and diversion of technical and management personnel. These lawsuits could hinder our ability to enter the market early with our product candidates and thereby hinder our ability to influence usage patterns when fewer, if any, of our potential competitors have entered such market, which could adversely impact our potential revenue from such product candidates or negatively impact our ability to gain market acceptance and market share for our products. We are currently involved in various ongoing litigation matters, as discussed elsewhere in this Annual Report on Form 10- K. Some of our competitors have substantially greater resources than we do and could be able to sustain the cost of litigation to a greater extent and for longer periods of time than we could. Furthermore, an adverse outcome of a dispute may require us: to pay damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed a party' s patent or other intellectual property rights; to cease making, licensing or using products that are alleged to incorporate or make use of the intellectual property of others; to expend additional development resources to reformulate our products or prevent us from marketing a certain drug; and to enter into potentially unfavorable royalty or license agreements in order to obtain the rights to use necessary technologies. Royalty or licensing agreements, if required, may be unavailable on terms acceptable to us, or at all. If we are unable to achieve and maintain adequate levels of coverage and reimbursement for our products or product candidates, if approved, their commercial success may be severely hindered. Successful sales of our products and any other approved product candidates depend on the availability of adequate coverage and reimbursement from third party payors. Patients who are prescribed medications for the treatment of their conditions generally rely on third party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental health care programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. In the United States, third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor- by- payor basis. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Reimbursement by a third party payor may depend upon a number of factors, including but not limited to, 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 / or neither cosmetic, experimental, nor investigational. Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may

require co- payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. In addition, the market for our products and our product candidates will depend significantly on access to third party payors' drug formularies, or lists of medications for which third party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access through formulary controls or otherwise to a branded drug when a less costly generic equivalent or other alternative is available. Further, coverage policies and third- party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Third party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling health care costs. In addition, in the United States, no uniform policy requirement for coverage and reimbursement for drug products exists among third party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that could require us to provide scientific, clinical and cost effectiveness support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to ~~achieve or~~ sustain profitability. Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third party coverage and reimbursement for our commercial products, and our pre- clinical and clinical product candidates for which we may receive regulatory approval, may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects. Current and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain for our products. The United States and some foreign jurisdictions are considering, or have enacted, a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products and our product candidates profitably, once they are approved for sale. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care 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. By way of example, in March 2010, the ACA was passed, which significantly changed health care financing by both governmental and private insurers. There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, ~~the Trump administration signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax- based shared responsibility payment imposed by the ACA~~ on ~~certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate. " Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA- mandated " Cadillac " tax on high- cost employer- sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point- of- sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the " donut hole. " On~~ June 17, 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. ~~Thus, the ACA will remain in effect in its current form.~~ Prior to the U. S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment for purposes of obtaining health insurance coverage through the ACA 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 ACA **. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and through a newly established manufacturer discount program** . It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact ACA and our business. We cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals for spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, triggering the legislation' s automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, which went into effect on April 1, 2013 and, following passage of the Bipartisan Budget Act of 2015 as well as certain legislative amendments, will remain in effect through 2031 ~~, except for a temporary suspension from May 1, 2020 through March 31, 2022~~

~~due to the COVID- 19 pandemic,~~ unless additional Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 3 % in the final fiscal year of this sequester. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Additionally, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U. S. Congressional inquiries, Presidential executive orders, and proposed and adopted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. **.** For example, the ~~Trump~~ **former U. S. Presidential** administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, ~~on July 24~~ **in May 2019** , ~~2020 and September 13, 2020,~~ the **Centers for Medicare & Medicaid Services, or CMS, issued** ~~Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration' s proposals. The FDA also released~~ a final rule **to allow Medicare Advantage Plans the** ~~and guidance in September 2020, implementing a portion --~~ **option** of **using step therapy** ~~the importation executive order providing guidance~~ for **Part B** ~~states to build and submit importation plans for~~ drugs **beginning** ~~from Canada. Further,~~ on ~~November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from~~ January 1, ~~2022~~ **2020** ~~to January 1, 2023 in response to ongoing litigation~~ . The ~~rule also creates a new safe harbor for price reductions reflected at the point- of- sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim~~ final rule **codified a CMS policy change that was** ~~implementing President Trump' s Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician- administered drugs to the lowest price paid in other economically advanced countries,~~ effective January 1, ~~2021 -~~ **2019** . **In** ~~. As~~ a **final rule issued by CMS** ~~result of litigation challenging the Most Favored Nation model,~~ on December ~~27~~ **31** , ~~2021~~ **2020 , CMS established a broader definition for a " line extension " drug such that the line extension of the initial brand name listed drug would not need to be an oral solid dosage form. This final rule may impact the rebate amounts associated with our products and negatively affect the commercial success of our products. Additionally, on December 2, 2020** , CMS published ~~a final rule~~ **changes to the Medicare Physician Fee Schedule for Calendar Year 2021** that ~~rescinded~~ **also may adversely impact** the **coverage and reimbursement of our products** ~~Most Favored Nation model interim final rule~~ . ~~In~~ **Under the changes, CMS assigned certain 505 (b) (2) drug products to existing multiple source drug codes because, according to CMS, some drug products approved under the 505 (b) (2) pathway share similar labeling and uses with generic drugs that are assigned to multiple source drug codes. CMS noted that this change was consistent with efforts to " curb drug prices " and encourages competition among products that are described by one billing code and share similar labeling. Additionally, in** July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to 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 as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. **In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single- source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries.** It is unclear whether these or similar policy initiatives will be implemented in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The full impact of these laws, as well as other new laws and reform measures that may be proposed and adopted in the future remains uncertain, but may result in additional reductions in Medicare and other health care funding, or higher production costs which could have a material adverse effect on our customers and, accordingly, our financial operations. Further, it is possible that additional governmental action is taken in response to the COVID- 19 pandemic. Risks Related to Our Reliance on Third Parties We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed. We have relied upon and plan to continue to rely upon third party CROs to monitor and manage data for our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory

responsibilities. We and our CROs are required to comply with FDA regulations and other laws regarding current good clinical practice, or GCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Council for Harmonization, or ICH, guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates are expected to be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process. Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. If any of our current strategic collaborators fail to perform their obligations or terminate their agreements with us, the development and commercialization of the product candidates under such agreements could be delayed or terminated and our business could be substantially harmed. In 2015, we entered into the Cephalon License, with Cephalon (Teva) for U. S. and Canadian rights to Bendeka for treatment of patients with CLL and patients with NHL. Pursuant to the terms of the Cephalon License, as has been amended from time to time, Teva is responsible for all U. S. commercial activities for the product including promotion and distribution, and we are responsible for obtaining and maintaining all regulatory approvals and conducting post- approval clinical studies. This strategic collaboration may not be scientifically or commercially successful due to a number of important factors, including the following: • If we fail to maintain any regulatory approvals, or otherwise materially breach the agreement, we may not receive all anticipated royalty payments; • Cephalon has significant discretion in determining the efforts and resources that it will apply to their strategic collaboration with us. The timing and amount of any cash payments, and royalties that we may receive under such agreements will depend on, among other things, the efforts, allocation of resources and the commercialization of our product by Cephalon under the Cephalon License; • Cephalon currently markets a competitive bendamustine product, Treanda ®, in the United States. In addition, it is possible that Cephalon may develop and commercialize, either alone or with others, or be acquired by a company that has, products that are similar to or competitive with the product candidates that they license from us; • Cephalon may change the focus of their commercialization efforts or pursue higher- priority programs; • Cephalon may terminate its strategic collaboration with us on short notice, which could make it difficult for us to attract new strategic collaborators or adversely affect how we are perceived in the scientific and financial communities; • Cephalon has the right to maintain or defend our intellectual property rights licensed to them in their territories, and, although we may have the right to assume the maintenance and defense of our intellectual property rights if they do not, our ability to do so may be compromised by our strategic collaborators' acts or omissions; and • Cephalon may not comply with all applicable regulatory requirements, or fail to report safety data in accordance with all applicable regulatory requirements; • If Cephalon fails to effectively commercialize our product, we may not be able to replace them with another collaborator, and, • If our agreement with Cephalon terminates, we are required to pay them a portion of our future profits on the product. Any of these events could have a material adverse effect on our business, results of operations and our ability to achieve future profitability, and could cause our stock price to decline. We may not be successful in maintaining development and commercialization collaborations, and any partner may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results. We have entered in licensing and / or collaboration agreements with third parties, including our license agreement with AOP Orphan for Landiolol and our strategic collaboration with Tyme **(now merged with Syros)** to advance oral SM- 88 for the treatment of patients with cancer. If we are able to establish additional collaboration arrangements, any such collaborations, in addition to our current license and collaboration agreements, may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and prospects. If we partner with a third

party for development and commercialization of a product or product candidate, we can expect to relinquish some or all of the control over the future success of that product or product candidate to the third party. It is possible that a partner may not devote sufficient resources to the development or commercialization of our product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such product candidate could be delayed or terminated and our business could be substantially harmed. In addition, the terms of any collaboration or other arrangement that we establish may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our common stock. In some cases, we may be responsible for continuing development of a product candidate or research program under a collaboration, and the payment we receive from our partner may be insufficient to cover the cost of this development. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement, and they may require substantial resources to maintain. We may be subject to a number of additional risks associated with our collaborations with third parties, the occurrence of which could cause collaboration arrangements to fail. Conflicts may arise between us and our partners, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a partner could act in its own self- interest, which may be adverse to our interests. Any such disagreement between us and a partner could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates and harm our business: • reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaboration arrangement; • actions taken by a partner inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; and • unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities. We rely on third parties to manufacture commercial supplies of our products and clinical supplies of our product candidates, and we intend to rely on third parties to manufacture commercial supplies of any other approved products. The commercialization of any of our products could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance. We do not own any manufacturing facilities, and we do not currently, and do not expect in the future, to independently conduct any aspects of our product manufacturing and testing, or other activities related to the clinical development and commercialization of our product candidates. We currently rely, and expect to continue to rely, on third parties with respect to these items, and control only certain aspects of their activities. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our product candidate development and product commercialization activities. Our reliance on these third parties reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards and any applicable trial protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, clinical trials required to support future regulatory submissions and approval of our product candidates. Our products and product candidates are highly reliant on very complex sterile techniques and personnel aseptic techniques. The facilities used by our third- party manufacturers to manufacture our products and product candidates must be approved by the applicable regulatory authorities pursuant to inspections that will be conducted after we submit our NDA to the FDA. If any of our third- party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third- party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Quality problems in manufacturing are linked to a majority of shortages of sterile injectable drugs. Some of the largest manufacturers of sterile injectable drugs have had serious quality problems leading to the temporary voluntary closure or renovations of major production facilities. Further, as we scale up manufacturing of our product candidates and conduct required stability testing, product packaging, equipment and process-related issues may require refinement or resolution in order for us to proceed with our planned clinical trials and obtain regulatory approval for commercialization of our product candidates. In the future, for example, we may identify impurities in the product manufactured for us for commercial supply, which could result in increased scrutiny by the regulatory agencies, delays in our clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our product candidates. If the FDA or any other applicable regulatory authority does not approve these facilities to manufacture our products or if they withdraw any such approval in the future, or if our suppliers or third- party manufacturers decide they no longer want to manufacture our products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products or product candidates. More generally, manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to make product candidates available for clinical trials and development purposes or to further commercialize our products or product candidates in the United States would be jeopardized. Any delay or interruption in our ability to meet commercial demand may result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for approved products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at

additional expense or terminate clinical trials completely. Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. Regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. The occurrence of any of these factors could have a material adverse effect on our business, results of operations, financial condition and prospects. The design, development, manufacture, supply, and distribution of our products and product candidates is highly regulated and technically complex. All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our products and product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late- stage clinical trials must be manufactured in accordance with cGMP and equivalent foreign standards. 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 adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our products or product candidates that may not be detectable in final product testing. The development, manufacture, supply, and distribution of our products, as well as our other product candidates, is highly regulated and technically complex. We, along with our third- party providers, must comply with all applicable regulatory requirements of the FDA and foreign authorities. We, or our contract manufacturers, must supply all necessary documentation in support of our regulatory filings for our products and product candidates on a timely basis and must adhere to the FDA' s good laboratory practices, or GLP, and cGMP regulations enforced by the FDA through its facilities inspection program, and the equivalent standards of the regulatory authorities in other countries. Any failure by our third- party manufacturers to comply with cGMP or failure to scale- up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Our facilities and quality systems and the facilities and quality systems of some or all of our third- party contractors must also pass a pre- approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities in any country may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities and quality systems do not pass a pre- approval plant inspection, FDA approval of our product candidates, or the equivalent approvals in other jurisdictions, will not be granted. Regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third- party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and / or time- consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. If we or any of our third- party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biological product or revocation of a pre- existing approval. As a result, our business, financial condition and results of operations may be materially harmed. We rely on limited sources of supply for our products and product candidates, and any disruption in the chain of supply may impact production and sales of our products and cause delay in developing and commercializing our product candidates. We currently have relationships with only one third party for the manufacture of each of our most advanced products and product candidates. Because of the unique equipment and process for manufacturing our products transferring manufacturing activities to an alternate supplier would be a time- consuming and costly endeavor, and there are only a limited number of manufacturers that we believe are capable of performing this function for us. Switching finished drug suppliers may involve substantial cost and could result in a delay in our desired clinical and commercial timelines. If any of these single- source manufacturers breaches or terminates their agreements with us, we would need to identify an alternative source for the manufacture and supply of product candidates to us for the purposes of our development and commercialization of the applicable products. Identifying an appropriately qualified source of alternative supply for any one or more of these product candidates could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our product candidates, which could harm our financial position and commercial potential for our products. Any alternative vendor would also need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if we appoint a new manufacturer for supply of our product candidates that differs from the manufacturer used for clinical development of such product candidates. For our other product candidates, we expect that only one supplier will initially be qualified as a vendor with the FDA. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply ~~. Additionally, if the COVID- 19 pandemic continues to persist for an extended period of time and impacts essential distribution systems, we could continue to experience disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products, which would adversely impact our ability to deliver products to clinical trial sites or to generate sales of and revenues from our approved products~~ . These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue. We may not be successful in establishing development and commercialization

collaborations which could adversely affect, and potentially prohibit, our ability to develop our product candidates. Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we are exploring collaborations with third parties outside of the United States that have more resources and experience. We may, however, be unable to advance the development of our products and product candidates in territories outside of the United States, which may limit the market potential for this product candidate. In situations where we enter into a development and commercial collaboration arrangement for a product candidate, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaboration arrangement for such product candidate. There are a limited number of potential partners, and we expect to face competition in seeking appropriate partners. We have entered into collaboration and promotion agreements with third parties, but there is no assurance these arrangements will be successful. If we are unable to enter into any future development and commercial collaborations and / or sales and marketing arrangements on acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our product candidates and / or effectively market and sell future approved products, if any, in all of the territories outside of the United States where it may otherwise be valuable to do so. If we are unable to maintain our GPO, relationships, our revenues could decline and future profitability could be jeopardized. Most of the end- users of injectable pharmaceutical products have relationships with GPOs whereby such GPOs provide such end- users access to a broad range of pharmaceutical products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug purchasing decisions of such end- users. Hospitals and other end-users contract with the GPO of their choice for their purchasing needs. We currently derive, and expect to continue to derive, a large percentage of our revenue from end- user customers that are members of a small number of GPOs. Maintaining strong relationships with these GPOs will require us to continue to be a reliable supplier, remain price competitive and comply with FDA regulations. The GPOs with whom we have relationships may have relationships with companies that sell competing products, and such GPOs may earn higher margins from these products or combinations of competing products or may prefer products other than ours for other reasons. If we are unable to maintain our GPO relationships, sales of our products and revenue could decline. We rely on a limited number of pharmaceutical wholesalers to distribute our products. As is typical in the pharmaceutical industry, we rely upon pharmaceutical wholesalers in connection with the distribution of our products. A significant amount of our products are sold to end- users under GPO pricing arrangements through a limited number of pharmaceutical wholesalers. If we are unable to maintain our business relationships with these pharmaceutical wholesalers on commercially acceptable terms, it could have a material adverse effect on our sales and may prevent us from achieving profitability. Our approved products may not achieve expected levels of market acceptance. Even if we are able to obtain regulatory approvals for our product candidates, the success of those products is dependent upon market acceptance. Levels of market acceptance for our product candidates could be affected by several factors, including: • the availability of alternative products from our competitors; • the price of our products relative to those of our competitors; • the timing of our market entry; • the ability to market our products effectively at the retail level; • the perception of patients and the healthcare community, including third- party payors, regarding the safety efficacy and benefits of our drug products compared to those of competing products; and • the acceptance of our products by government and private formularies. Some of these factors are not within our control, and our products may not achieve expected levels of market acceptance. Additionally, continuing and increasingly sophisticated studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others which may call into question the utilization, safety and efficacy of previously marketed products. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other risk management programs such as the need for a patient registry. Risks Related to Our Business Operations and Industry **We may engage in strategic transactions to acquire assets, businesses, or rights to products, product candidates or technologies or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt, or cause us to incur significant expense. As part of our business strategy, we may engage in additional strategic transactions to expand and diversify our product pipeline, including through the acquisition of assets, businesses, or rights to products, product candidates or technologies or through strategic alliances or collaborations, similar to our acquisition of Acacia and investment in Enalare. We may not identify suitable strategic transactions, or complete such transactions in a timely manner, on a cost- effective basis, or at all. Moreover, we may devote resources to potential opportunities that are never completed or we may incorrectly judge the value or worth of such opportunities. Even if we successfully execute a strategic transaction, we may not be able to realize the anticipated benefits of such transaction, may incur additional debt or assume unknown or contingent liabilities in connection therewith, and may experience losses related to our investments in such transactions. Integration of an acquired company or assets into our existing business may not be successful and may disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, and require management resources that would otherwise focus on developing our existing business. Even if we are able to achieve the long- term benefits of a strategic transaction, our expenses and short- term costs may increase materially and adversely affect our liquidity. Any of the foregoing could have a detrimental effect on our business, results of operations and financial condition. In addition, potential future strategic transactions may entail numerous operational, financial and legal risks, including: • incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions; • exposure to known and unknown liabilities, including possible intellectual property infringement claims, violations of laws, tax liabilities and commercial disputes; • higher than expected acquisition and integration costs; • difficulty in integrating operations and personnel of any acquired business; • increased amortization expenses or, in the event that we write- down the value of acquired assets, impairment losses; • impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership; • inability to retain**

personnel, customers, distributors, vendors and other business partners integral to an in- licensed or acquired product, product candidate or technology; • potential failure of the due diligence processes to identify significant problems, liabilities or other shortcomings or challenges; • entry into indications or markets in which we have no or limited direct prior development or commercial experience and where competitors in such markets have stronger market positions; and • other challenges associated with managing an increasingly diversified business. If we are unable to successfully manage any strategic transaction in which we may engage, our ability to develop and commercialize new products and continue to expand and diversify our product pipeline may be limited. We may fail to realize all of the anticipated benefits of the Acacia acquisition, those benefits may take longer to realize than expected, or we may encounter integration difficulties. Our ability to realize the anticipated benefits of our Acacia acquisition will depend, to a large extent, on our ability to continue integrating Acacia and BARHEMSYS and BYFAVO, into our business and realize anticipated growth opportunities and synergies. We have devoted and will need to continue to devote significant management attention and resources to integrating these products into our business. The process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of the transaction could adversely affect our business, financial condition and results of operations. Our ability to realize the anticipated benefits of the transaction is expected to entail numerous material potential difficulties, including, among others: • the effectiveness of our sales force; • the level of orders submitted by wholesalers, hospitals and surgery centers; • the level of institutional demand for our products; • unit sales prices, [net of any sales reserves]; • the diversion of management attention to integration matters; • difficulties in achieving anticipated business opportunities and growth prospects from the acquisition; • difficulties in assimilating employees; and • potential unknown liabilities, adverse consequences, unforeseen increased expenses or other unanticipated problems associated with the transaction. Many of these factors are outside of our control, and any one of them could result in increased costs, decreased expected revenues and further diversion of management time and energy, which could materially impact our business, financial condition and results of operations. In addition, we now possess not only the rights to BARHEMSYS and BYFAVO, but also certain corresponding liabilities and obligations, including the contractual liabilities and regulatory obligations that we have assumed upon closing of the transaction, including certain post- marketing commitments. Failure to satisfy any such requirements could delay our realization of, or prevent us from ever realizing, the anticipated benefits from the transaction. Further, it is possible that undisclosed, contingent, or other liabilities or problems may arise in the future of which we were previously unaware. These undisclosed liabilities could have an adverse effect on our business, financial condition and results of operations. All of these factors could decrease or delay the expected accretive effect of the transaction and negatively impact our stock price. As a result, it cannot be assured that our Acacia acquisition will result in the full realization of the benefits anticipated from the transaction within the anticipated time frames or at all. In addition, we may not realize some or all of the anticipated benefits of our investment in Enalare. Our ability to realize the anticipated benefits of our investment in Enalare will depend, to a large extent, on potential FDA submission, partnership with Biomedical Advanced Research and Development Authority and Orphan Drug Designation of ENA- 001. There is no assurance that these development programs and regulatory activities will be completed successfully. In addition, pursuant to the terms of the Purchase Agreement, we are obligated to further invest in Enalare, including two additional $ 15. 0 million milestone payments upon achievement of the milestones specified in the Purchase Agreement. The first $ 15. 0 million investment shall occur upon the dosing of the first patient in a Phase 2 human clinical trial of any product containing the active ingredient ENA-001. The second $ 15. 0 million investment shall occur when patient enrollment in the Phase 2 human clinical trial of a Product Candidate reaches 50 %. We also have the option to acquire all of the remaining outstanding shares of Enalare other than those already owned by us subject to the terms and conditions of the agreement. Given our rights and obligations under the Enalare agreement, we may forego or delay pursuit of other opportunities that may have proven to have greater commercial potential. In addition, we may forego our option to acquire Enalare. There is no assurance that Enalare' s development programs will be successful and that the milestones will be achieved in the expected timeframe, or at all, or that we will exercise the option to purchase the remaining Enalare shares if and when such option were to become available. All of these factors could negatively impact our stock price. We may expend our resources to pursue a particular product, product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. We focus on products, research programs and product candidates for specific indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. For example, in connection with our acquisition of Acacia, we paid to the Acacia securityholders (i) cash consideration of approximately $ 76 million, and (ii) 516, 024 shares of our common stock. We may never realize the anticipated benefits of the acquisition of Acacia and by investing our resources in BARHEMSYS and BYFAVO, we may be required to forgo or delay other opportunities. In addition, we and our collaboration partners have previously commenced clinical trials that were not successful for a number of reasons, including inconsistent or negative data and difficulties identifying qualified patients. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. Notwithstanding our large investments to date and anticipated future expenditures in proprietary technologies for both small- molecule and gene therapy drug discovery, to date we have been granted marketing authorization for a limited number of commercial products and have only recently achieved profitability. We may never realize a return on investment. We may not be able to successfully renew or satisfy the ongoing requirements of our current marketing authorizations for our current products and we may

never successfully develop any other marketable drugs or indications using our scientific approach. As a result of pursuing the development of product candidates using our proprietary technologies, we may fail to develop product candidates or address indications based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success. Research programs to identify new product candidates require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Further, even if we could successfully develop new products or indications, we may make a strategic decision to discontinue development of a product candidate or indication if, for example, we believe commercialization will be difficult relative to the standard of care or we prefer to pursue other opportunities in our pipeline. For example, in the first quarter of 2023 we decided to exit the vasopressin market by discontinuing all related manufacturing and halting sales beyond current inventory levels that are expected to be depleted by the end of the second quarter of 2023. Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. We are highly dependent on the principal members of our executive team, which include our Chief Executive Officer and President, **and** Chief Financial ~~Officer, Chief Medical Officer, and Chief Commercial~~ Officer. We are currently searching for a new Chief Medical Officer, which position is currently vacant. The loss of these executives' services may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are" at will" employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit key executives or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives. We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations. As of December 31, ~~2021~~ **2022** , we had a total of ~~102~~ **134** employees in the United States **and one employee in the United Kingdom** . As our company matures, we expect to expand our employee base to increase our managerial, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day- to- day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations which may result in weaknesses in our infrastructure and give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and / or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to sell our products and commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth .~~-~~We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability. The use of our product candidates in clinical trials (if any), and the sale of our products and any product candidates for which we obtain marketing approval, exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products, other approved future products and our product candidates. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in: • impairment of our business reputation; • withdrawal of clinical study participants; • costs due to related litigation; • distraction of management' s attention from our primary business; • substantial monetary awards to patients or other claimants; • the inability to commercialize our product candidates; and • decreased demand for our products and our product candidates, if approved for commercial sale. Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business. We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences. In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (commonly known as processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about participants in connection with clinical trials, and sensitive third- party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and

other obligations that govern the processing of personal data by us and on our behalf. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Additionally, the California Consumer Privacy Act of 2018, or CCPA, imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $ 7, 500 per violation) and a private right of action for certain data breaches. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. In addition, it is anticipated that the California Privacy Rights Act of 2020, or CPRA, effective January 1, 2023, will expand the CCPA. The CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts. Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union' s General Data Protection Regulation, or EU GDPR, and the United Kingdom' s GDPR, or UK GDPR, impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4 % of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to the processing of their personal data. Certain jurisdictions have enacted data localization laws and cross- border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross- border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the European Economic Area, or EEA, that the European Commission does not consider to provide an adequate level of data privacy and security, such as the United States. The European Commission released a set of " Standard Contractual Clauses, " or SCCs, that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA, but there exists some uncertainty regarding whether the SCCs will remain a valid mechanism. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at- issue personal data. In addition, Switzerland and the UK similarly restrict personal data transfers outside of those jurisdictions to countries, such as the United States, that do not provide an adequate level of personal data protection, and certain countries outside Europe (e. g., China) have also passed or are considering laws requiring local data residency or otherwise impeding the transfer of personal data across borders, any of which could increase the cost and complexity of doing business. If we cannot implement a valid compliance mechanism for cross- border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities; limiting our ability to collaborate with parties that are subject to such cross- border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense. Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third- party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- related claims); additional reporting requirements and / or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions in our business operations; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations. If our information technology systems or sensitive information, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences. In the ordinary course of our business, we may process proprietary, confidential, and sensitive data, including personal data (such as health- related data), intellectual property,

and trade secrets (collectively, sensitive information). We may rely upon third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud- based infrastructure, encryption and authentication technology, employee email, 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. We may share or receive sensitive information with or from third parties. Cyberattacks, malicious internet- based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer " hackers, " threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including, without limitation, nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. We and the third parties upon which we rely may be subject to a variety of evolving threats, including, but not limited to, social- engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, and other similar threats. Ransomware attacks, including by organized criminal threat actors, nation- states, and nation- state- supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data 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. Similarly, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third- party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third- party information technology systems that support us and our business operations. The COVID- 19 pandemic and our **continuing** remote workforce poses increased risks to our information technology systems and data, as more of our employees work from home, utilizing network connections outside our premises. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to operate our business. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry- standard or reasonable security measures to protect our information technology systems and sensitive information. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Business interruptions could delay us in the process of developing our product candidates and could disrupt our sales of any products we may sell. Our headquarters are located in Woodcliff Lake, New Jersey. If we encounter any disruptions to our operations at this building or if it were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute or other unforeseen disruption, then we may be prevented from effectively operating our business. We do not carry insurance for natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations. We may be constrained by our obligations under our ~~Revised~~ **Third Amended** Credit Agreement to operate our business to its full potential. **On November 1, 2022, we entered into the Third Amended and Restated Credit Agreement (the " Third Amended Credit Agreement "), with JPMorgan Chase Bank, N. A., as administrative agent (the " Administrative Agent ") and the lenders party thereto, which replaced our prior credit agreement, dated as of November 8, 2019 (the " Second Amended Credit Agreement "). The terms and amounts borrowed under the Third Amended Credit Agreement includes a drawn term loan of $ 50 million and a $ 100 million revolving credit facility of which $ 15. 0 million was drawn on November 1, 2022. In addition, approximately $ 35. 4 million of the proceeds of the credit facility were used to refinance all amounts outstanding under the Second Amended**

Credit Agreement. All amounts outstanding under the Third Amended Credit Agreement shall be due and payable on October 31, 2025, unless otherwise accelerated or extended pursuant to the terms of the Third Amended Credit Agreement. Our ~~Revised~~ **Third Amended** Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants **applicable to us and our consolidated subsidiaries** , including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. Under the terms of the ~~Revised~~ **Third Amended** Credit Agreement, we are required to comply with (a) a **maximum total net leverage ratio, (b) a fixed charge coverage ratio and (c) a minimum liquidity covenant. These terms may restrict our ability to operate our business in the manner we deem most effective or desirable, and may restrict our ability to fund our operations through new offerings of our common stock or strengthen our candidate development pipeline through acquisitions or licenses which would cause us to exceed our** maximum senior secured net leverage ratio ~~; (b) a maximum total net leverage ratio and (c) a minimum fixed charge coverage ratio. These terms may restrict our ability to operate our business in the manner we deem most effective or desirable, and may restrict our ability to fund our operations through new public offerings of our common stock or strengthen our candidate development pipeline through acquisitions or licenses which cause us to exceed our maximum senior secured net leverage ratio~~ . Failure to comply with the representations and warranties or affirmative and negative covenants could constitute an event of default which, if continued beyond ~~the~~ **any applicable** cure period, would allow the ~~administrative~~ **Administrative** ~~agent~~ **Agent** , at the request of or with the consent of the lenders holding a majority of the loans and commitments under the facility, to terminate the commitments of the lenders to make further loans and declare all the obligations of the loan parties under the ~~Revised~~ **Third Amended** Credit Agreement to be immediately due and payable, either of which could harm **our business. In addition, our obligations under the Third Amended Credit Agreement are secured by a pledge of substantially all of our assets. If we are unable to pay our obligations when due, the Administrative Agent on behalf of the lenders could proceed to protect and enforce their rights under the Third Amended Credit Agreement, including by foreclosure on the assets securing our obligations under the Third Amended Credit Agreement). The foregoing would materially and adversely affect** our business. Risks Related to Our Intellectual Property If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market. We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and our product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in- license may fail to result in issued patents with claims that cover the products in the United States or in foreign countries or territories. If this were to occur, early generic competition could be expected against our products and our product candidates in development. There may be relevant prior art relating to our patents and patent applications which could invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the active pharmaceutical ingredients in many of our product candidates have been on the market as separate products for many years, it is possible that these products have previously been used off- label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Any adverse outcome in these types of matters could result in one or more generic versions of our products being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to increase sales of our products and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to our products or product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them and threaten our ability to commercialize our product candidates. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. Further, if we encounter delays in regulatory approvals, the period of time during which we could market our product candidates under patent protection could be reduced. If third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development and reformulation processes that involve proprietary know- how, information or technology that is not covered by patents. For example, we maintain trade secrets with respect to certain of the formulation and manufacturing techniques related to our products and our product candidates. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know- how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. Our ability to obtain patents

is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy- Smith Act has also introduced procedures making it easier for third- parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy- Smith Act contains new statutory provisions that still require the USPTO to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is too early to tell what, if any, impact the Leahy- Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy- Smith 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. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. If we are unable to prevent material disclosure of the non- patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. Our drug development strategy relies heavily upon the 505 (b) (2) regulatory pathway, which requires us to certify that we do not infringe upon third- party patents covering approved drugs. Such certifications typically result in third- party claims of intellectual property infringement, the defense of which will be costly and time consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business. Litigation or other proceedings to enforce or defend intellectual property rights are often complex in nature, may be very expensive and time- consuming, may divert our management' s attention from other aspects of our business and may result in unfavorable outcomes that could adversely impact our ability to launch and market our product candidates, or to prevent third parties from competing with our products and product candidates. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the USPTO. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. In particular, our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505 (b) (2) regulatory pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA' s Orange Book with respect to our NDA; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. When we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to the patent owner once our 505 (b) (2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit against us to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our NDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45- day period, our NDA will not be subject to the 30- month stay. In addition to paragraph IV litigation noted above, third- party owners of patents may generally assert that we are employing their proprietary technology without authorization. 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 our products and / or our product candidates. Because patent applications can take many years to issue, there may be currently pending or subsequently filed patent applications which may later result in issued patents that may be infringed by our products or product candidates. If any third- party patents were held by a court of competent jurisdiction to cover aspects of our product candidates, including the formulation, method of use, any method or process involved in the manufacture of any of our product candidates, any molecules

or intermediates formed during such manufacturing process or any other attribute of the final product itself, the holders of any such patents may be able to block our ability to commercialize our product candidates unless we obtain a license under the applicable patents, or until such patents expire. In either case, such a license may not be available on commercially reasonable terms or at all. Parties making claims against us may request and / or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates on a temporary or permanent basis. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products or manufacturing processes, 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, manufacture clinical trial supplies or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties. If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business. We are a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. Our existing license agreements impose, and we expect that future license agreements will impose, on us, various development, regulatory and / or commercial diligence obligations, payment of milestones and / or royalties and other obligations. Additionally, one of our existing license agreements is a sublicense from a third party who is not the original licensor of the intellectual property at issue. Under these agreements, we must rely on our licensor to comply with their obligations under the primary license agreements under which such third party obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If our licensors fail to comply with their obligations under these upstream license agreements, the original third- party licensor may have the right to terminate the original license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do at a reasonable cost or on reasonable terms, which may impact our ability to continue to develop and commercialize our product candidates and companion diagnostic incorporating the relevant intellectual property. If we fail to comply with our obligations under our license agreements, or we are subject to a bankruptcy or insolvency, the licensor may have the right to terminate the license. In the event that any of our important technology licenses were to be terminated by the licensor, we would likely cease further development of the related program or be required to spend significant time and resources to modify the program to not use the rights under the terminated license. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful. Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not being issued. Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. 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. 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. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. The patents and the patent applications that we have covering our products are limited to specific formulations, methods of use and processes, and our market opportunity for our products and our product candidates may be limited by the lack of patent protection for the active ingredients and by competition from other formulations and delivery methods that may be developed by competitors. Patent protection on the active ingredients in our currently marketed products (Ryanodex, Bendeka, Argatroban and Non- Alcohol Docetaxel Injection) has expired, and there is therefore no composition of matter patent protection available for the active ingredient in such products. This is also the case with respect to our other product candidates. We have obtained, and continue to seek to obtain patent protection of other aspects of our products and our product candidates, including specific formulations, methods of use and processes, which may not be as effective as composition of matter coverage in preventing workarounds by competitors. As a result, generic products that do not infringe the claims of our issued patents covering formulations, methods of use and processes are, or may be, available while we are marketing our products. Competitors who obtain the requisite regulatory approval could be able to commercialize products with the same active

ingredients as our product candidates so long as the competitors do not infringe any process, use or formulation patents that we have developed for our products, subject to any regulatory exclusivity we may be able to obtain for our products. The number of patents and patent applications covering products containing the same active ingredient as our products and our product candidates indicates that competitors have sought to develop and may seek to commercialize competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for our products and our product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of our products and our product candidates that are different from ours and do not infringe our issued patents covering our products. Ryanodex ® (dantrolene sodium), Belrapzo, Bendeka, ~~Pemfexy~~ and ~~vasopressin~~ **PEMFEXY** among other products have been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. Once our products are on the market, one or more third parties may also challenge the patents that we control covering our products, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products. 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. Ryanodex, Belrapzo, Bendeka, ~~Pemfexy~~ and ~~vasopressin~~ **PEMFEXY** , among other of our products, have been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. One or more third parties may also challenge the patents that we control covering our products in court or the USPTO, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products. If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post grant review, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our products or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or product candidates. Such a loss of patent protection could have a material adverse impact on our business. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. 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 application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non- compliance 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. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our products and product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business, financial condition and results of operations. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products or product candidates and companion diagnostic. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative: • others may be able to make compounds that are similar to our products or product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed; • we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed; • we or our licensors or future collaborators might not have been the first to file patent applications covering certain of

our inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our pending patent applications will not lead to issued patents; • issued patents that we own or have exclusively licensed may be held invalid or unenforceable as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; and • the patents of others may have an adverse effect on our business, financial condition and results of operations. Should any of these events occur, they could significantly harm our business, results of operations and prospects. Risks Related to Ownership of Our Common Stock Our stock price may continue to fluctuate significantly. The trading price of our common stock has fluctuated significantly in the past and is likely to continue to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following: • any delay in filing an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA' s review of that NDA; • failure to successfully execute our commercialization strategy with respect to our approved products or any other approved product in the future; • adverse results or delays in clinical trials, if any; • significant lawsuits, including patent or stockholder litigation; • inability to obtain additional funding; • failure to successfully develop and commercialize our product candidates; • changes in the structure of healthcare payment systems; • changes in laws or regulations applicable to our product candidates; • inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices; • unanticipated serious safety concerns related to the use of our products or any of our product candidates; • adverse regulatory decisions; • introduction of new products or technologies by our competitors; • entry into new markets by our competitors; • failure to meet or exceed product development or financial projections we provide to the public; • failure to meet or exceed the estimates and projections of the investment community; • issuance of new or updated research or reports by securities analysts; • fluctuations in the valuation of companies perceived by investors to be comparable to us; • the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community; • announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • additions or departures of key scientific or management personnel; • changes in the market valuations of similar companies; • sales of our common stock by us or our stockholders in the future; • the trading volume of our common stock; • changes in the collective short interest in our common stock; • additional repurchases of our common stock, if any, pursuant to our current share repurchase program ~~.~~ **; and** • **general economic, industry and market conditions, including the** impacts **thereon** of ~~the~~ **inflation and rising interest rates,** COVID- 19 ~~pandemic~~ , **Russia' s invasion of Ukraine** and **global geopolitical tensions** ~~• general economic and market conditions~~ . These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. For example, in May 2016, we became party to a federal securities class action lawsuit, and although it was dismissed in October 2017, we incurred substantial costs defending such lawsuit. Such lawsuit, as well as similar lawsuits instituted in the future, could result in substantial additional costs to us and could also divert the time and attention of our management. 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. As of December 31, ~~2021~~ **2022** , our executive officers, directors, 5 % or greater stockholders and their affiliates beneficially own a significant percentage of our voting stock. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to influence all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to influence elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders. Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall. Sales of a substantial number of shares of our common stock by our existing stockholders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of ~~February 28~~ **March 16** , ~~2022~~ **2023** we had ~~12~~ **13** , ~~697~~ **084** , ~~101~~ **243** shares of common stock outstanding, all of which **are eligible for sale in the public market** , other than shares held by our directors and certain officers ~~,~~ **which** are ~~eligible for sale in the public market,~~ subject in some cases to compliance with the requirements of Rule 144, including volume limitations and manner of sale requirements. In addition, shares issued upon exercise of vested options are eligible for sale. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.. Future issuances of our common stock or rights to purchase our common stock, including in connection with potential business development transactions we may determine to pursue and / or pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We expect that significant additional capital will be needed in the future to continue our planned operations and / or in connection with potential business development transactions we may determine to pursue. To the extent we raise additional capital or pursue potential business

development transactions by issuing equity securities, our stockholders may experience substantial dilution. We currently have on file with the SEC a shelf registration statement, which allows us to offer and sell certain registered securities, such as common stock, preferred stock, debt securities and warrants, from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. We may sell common stock, convertible securities or other equity or debt securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity or debt securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. Pursuant to our 2014 Equity Incentive Plan, or the 2014 Plan, our management is authorized to grant stock options and other equity awards to our employees, directors and consultants. We have issued a significant number of stock options and other equity awards under the 2014 Plan. The shares underlying these awards are registered on a Form S- 8 registration statement. As a result, upon vesting these shares can be freely exercised and sold in the public market upon issuance, subject to volume limitations applicable to affiliates. The exercise of options and the subsequent sale of the underlying common stock could cause a decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. In addition, the number of shares available for future grant under the 2014 Plan will automatically increase each year by 6 % of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2014 Plan each year. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall. We do not intend to pay cash dividends on our common stock so any returns will be limited to the value of our stock. We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determinations to pay cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions (such as our ~~Revised~~ **Third Amended** Credit Agreement), general business conditions, and any other factors that our board of directors may deem relevant. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no assurance that our Share Repurchase Program will result in repurchases of our common stock or enhance long term stockholder value. Repurchases of our common stock pursuant to our Share Repurchase Program could affect our stock price and increase its volatility and will reduce the market liquidity for our stock. The existence of a share repurchase program could also cause our stock price to be higher than it would be in the absence of such a program. Additionally, any future repurchases would diminish our cash reserves, which could impact our ability to pursue possible future strategic opportunities and acquisitions. There can be no assurance that any stock repurchases will, in fact, occur, or, if they occur, that they will enhance stockholder value. Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management. Some provisions of our charter documents and Delaware law may have anti- takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include: • authorizing the issuance of" blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval; • limiting the removal of directors by the stockholders; • creating a classified board of directors; • prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; • eliminating the ability of stockholders to call a special meeting of stockholders; and • establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us. Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for certain 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 employees. Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any derivative action or proceeding brought on behalf of the Company, any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company' s stockholders, any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or any action asserting a claim governed by the internal affairs doctrine. This forum selection provision does not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act or any claim for which the federal courts have exclusive jurisdiction. This forum selection provision may limit a stockholder' s ability to bring certain claims in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. If a court were to find this forum selection provision 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. General Risk Factors We are at risk of securities class action and similar litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. On May 31, 2016, a federal securities class action suit was brought against us seeking compensatory damages in connection with, among other things, the CRL we received with respect to our NDA for EP- 6101. Such lawsuit was dismissed with prejudice in August 2017, however, any similar litigation in the future, could result in substantial cost and a diversion of management' s attention and resources, which could harm our business. **Unstable market, economic and geopolitical conditions may have serious adverse consequences on our business, financial condition and stock price. The global credit and financial markets have experienced extreme volatility and disruptions, including as a result of inflation and rising interest rates, COVID- 19, Russia' s invasion of Ukraine and global geopolitical tension, and may experience disruptions in the future. These disruptions can result in severely diminished liquidity and credit availability, increase in inflation, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment, higher inflation, 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 have a material adverse effect on our operations, 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 or rising inflation, which could directly affect our ability to attain our operating goals on schedule and on budget. Other international and geopolitical events could also have a serious adverse impact on our business. For instance, in February 2022, Russia initiated military action against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions. While we cannot predict the broader consequences, the conflict and retaliatory and counter- retaliatory actions could materially adversely affect global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.** We have incurred significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives. As a public company, we incur significant ongoing legal, accounting and other expenses. For example, we are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. We have incurred and will continue to incur costs associated with the preparation in filing of these reports. In addition, the Sarbanes- Oxley Act, as well as rules subsequently implemented by the SEC, and Nasdaq have imposed various other requirements on public companies and we have incurred and will continue to incur costs associated with compliance with such requirements. In July 2010, the Dodd- Frank Wall Street Reform and Consumer Protection Act, or the Dodd- Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd- Frank Act that required the SEC to adopt additional rules and regulations in these areas such as" say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time- consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage. ~~64~~ **70**