Risk Factors Comparison 2024-04-16 to 2023-04-10 Form: 10-K

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An investment in our common stock involves a high degree of risk. Before making an investment decision, you should give careful consideration to the following risk factors, in addition to the other information included in this Annual Report, including our consolidated financial statements and related notes, before deciding whether to invest in shares of our common stock. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment. Risks Related to Our Business We have incurred losses since inception, anticipate that we will incur continued losses for the foreseeable future indicating the possibility that we may not be able to operate in the future. For the years ended December 31, **2023 and** 2022 ~~and 2021~~, we had an accumulated deficit of $ **224. 6 million, and $** 175. 7 ~~million, and $ 133. 5~~ million, respectively. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development efforts, continue our clinical trials, acquire or license technologies, advance other product candidates into clinical development, complete clinical trials, seek regulatory approval and, if we receive FDA approval, commercialize our products. In November 2020 and February 2021, we raised net proceeds of approximately $ 31. 6 million and $ 82. 1 million, respectively, to fund our future operations. The consolidated financial statements included in this Annual Report on Form 10- K have been prepared under the assumption that we will continue as a going concern. Due to our recurring and expected continuing losses from operations, we have concluded there is substantial doubt in our ability to continue as a going concern within one year of the issuance of these consolidated financial statements without additional capital becoming available ~~to attain further operating efficiencies and, ultimately, to generate revenue~~. ~~The consolidated financial statements do not include any adjustments that might result from~~ **In October 2023 and February 2024, we raised $ 5. 0 million and $ 2. 0 million, respectively through** the ~~outcome~~ **sale** of ~~this uncertainty~~ **common stock and warrants**. Our ability to raise additional funds is contingent upon, among other factors, the sale of the shares of our common stock or obtaining alternate financing. We cannot provide any assurance that we will be able to raise additional capital. If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our clinical and regulatory efforts, which is critical to the realization of our business plan. The accompanying consolidated financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern. It is not possible for us to predict at this time the potential success of our business. The revenue and income potential of our business and operations are currently unknown. If we cannot continue as a viable entity, you may lose some or all of your investment in our company. Our product candidate rencofilstat is in the early stages of development and its commercial viability remains subject to the successful outcome of current and future preclinical studies, clinical trials, regulatory approvals and the risks generally inherent in the development of a pharmaceutical product candidate. If we are unable to successfully advance or develop our product candidate, our business will be materially harmed. In the near- term, failure to successfully advance the development of our product candidates may have a material adverse effect on us. To date, we have not successfully developed or commercially marketed, distributed or sold any product candidate. The success of our business depends primarily upon our ability to successfully advance the development of our product candidates through preclinical studies and clinical trials, have these product candidates approved for sale by the FDA or regulatory authorities in other countries, and ultimately have these product candidates successfully commercialized by us or a strategic partner. We cannot assure you that the results of our ongoing preclinical studies or clinical trials will support or justify the continued development of our product candidates, or that we will receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidates. Our product candidates must satisfy rigorous regulatory standards of safety and efficacy before we can advance or complete their clinical development, or they can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy preclinical studies and clinical trials, develop acceptable manufacturing processes, and obtain regulatory approval of our product candidates. Despite these efforts, our product candidates may not: • offer therapeutic or other medical benefits over existing drugs or other product candidates in development to treat the same patient population; • be proven to be safe and effective in current and future preclinical studies or clinical trials; • have the desired effects; • be free from undesirable or unexpected effects; • meet applicable regulatory standards; • be capable of being formulated and manufactured in commercially suitable quantities and at an acceptable cost; or • be successfully commercialized by us or by collaborators. Even if we demonstrate favorable results in preclinical studies and early- stage clinical trials, we cannot assure you that the results of late- stage clinical trials will be favorable enough to support the continued development of our product candidates. Several companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late- stage clinical trials, even after achieving promising results in preclinical testing or early- stage clinical trials. Accordingly, results from completed preclinical studies and early- stage clinical trials of our product candidates may not be predictive of the results we may obtain in later- stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving our product candidates demonstrate a satisfactory safety and efficacy profile, such results may not be sufficient to support the submission of a New Drug Application, or NDA or a biologics license application, or BLA to obtain regulatory approval from the FDA in the U. S., or other similar regulatory agencies in other jurisdictions, which is required to market and sell the product. Our product candidates will require significant additional research and development efforts, the commitment of substantial

financial resources, and regulatory approvals prior to advancing into further clinical development or being commercialized by us or collaborators. We cannot assure you that our product candidates will successfully progress through the drug development process or will result in commercially viable products. We do not expect our product candidates to be commercialized by us or collaborators for at least several years. Our product candidate may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products or investigational new drugs, which may delay or preclude further development or regulatory approval or limit their use if approved. Throughout the drug development process, we must continually demonstrate the safety and tolerability of our product candidate to obtain regulatory approval to further advance clinical development or to market them. Even if our product candidate demonstrates biologic activity and clinical efficacy, any unacceptable adverse side effects or toxicities, when administered alone or in the presence of other pharmaceutical products, which can arise at any stage of development, may outweigh potential benefits. In preclinical studies and clinical trials were conducted to date, our product candidate has demonstrated an acceptable safety profile, although these studies and trials have involved a small number of subjects or patients over a limited period of time. We may observe adverse or significant adverse events or drug- drug interactions in future preclinical studies or clinical trial candidates, which could result in the delay or termination of development, prevent regulatory approval, or limit market acceptance if ultimately approved. If the results of preclinical studies or clinical trials for our product candidate, including those that are subject to existing or future license or collaboration agreements, are unfavorable or delayed, we could be delayed or precluded from the further development or commercialization of our product candidate, which could materially harm our business. In order to further advance the development of, and ultimately receive regulatory approval to sell, our product candidate, we must conduct extensive preclinical studies and clinical trials to demonstrate their safety and efficacy to the satisfaction of the FDA or similar regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can occur at any time, or in any phase of preclinical or clinical testing, and can result from concerns about safety or toxicity, a lack of demonstrated efficacy or superior efficacy over other similar products that have been approved for sale or are in more advanced stages of development, poor study or trial design, and issues related to the formulation or manufacturing process of the materials used to conduct the trials. The results of prior preclinical studies or clinical trials are not necessarily predictive of the results we may observe in later stage clinical trials. In many cases, product candidates in clinical development may fail to show desired safety and efficacy characteristics despite having favorably demonstrated such characteristics in preclinical studies or earlier stage clinical trials. In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive regulatory approval for, or commercialize our product candidate, including, but not limited to: • communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials; • regulatory authorities (including an Institutional Review Board or Ethical Committee) or IRB or EC, not authorizing us to commence or conduct a clinical trial at a prospective trial site; • enrollment in our clinical trials being delayed, or proceeding at a slower pace than we expected, because we have difficulty recruiting patients or participants dropping out of our clinical trials at a higher rate than we anticipated; • our third- party contractors, upon whom we rely for conducting preclinical studies, clinical trials and manufacturing of our trial materials, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner; • having to suspend or ultimately terminate our clinical trials if participants are being exposed to unacceptable health or safety risks; • IRBs, ECs or regulators requiring that we hold, suspend or terminate our preclinical studies and clinical trials for various reasons, including non-compliance with regulatory requirements; and • the supply or quality of drug material necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable. Even if the data collected from preclinical studies or clinical trials involving our product candidate demonstrate a satisfactory safety and efficacy profile, such results may not be sufficient to support the submission of an NDA or BLA to obtain regulatory approval from the FDA in the U. S., or other similar foreign regulatory authorities in foreign jurisdictions, which is required to market and sell the product. If third party vendors upon whom we intend to rely on to conduct our preclinical studies or clinical trials do not perform or fail to comply with strict regulations, these studies or trials of our product candidate may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business. We have limited resources dedicated to designing, conducting and managing preclinical studies and clinical trials. We intend to rely on third parties, including clinical research organizations, consultants and principal investigators, to assist us in designing, managing, monitoring and conducting our preclinical studies and clinical trials. We intend to rely on these vendors and individuals to perform many facets of the drug development process, including certain preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol, including safety monitoring and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our product candidate may be delayed or prove unsuccessful. Further, the FDA, or other similar foreign regulatory authorities, may inspect some of the clinical sites participating in our clinical trials in the U. S., or our third- party vendors' sites, to determine if our clinical trials are being conducted according to Good Clinical Practices or GCPs. If we or the FDA determine that our third- party vendors are not in compliance with, or have not conducted our clinical trials according to, applicable regulations we may be forced to delay, repeat or terminate such clinical trials. We have limited capacity for recruiting and managing clinical trials, which could impair our timing to initiate or complete clinical trials of our product candidate and materially harm our business. We have limited capacity to recruit and manage the clinical trials necessary to obtain FDA approval or approval by other regulatory authorities. By contrast, larger pharmaceutical and bio- pharmaceutical companies often have substantial staff with extensive experience in conducting clinical trials with multiple product candidates across multiple indications. In addition, they may have greater

financial resources to compete for the same clinical investigators and patients that we are attempting to recruit for our clinical trials. If approved and commercialized, rencofilstat intends to compete with numerous therapies for the treatment of NASH that are currently in development. To our knowledge, other potential competitors are in both later and earlier stages of development. If potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for rencofilstat. As a result, we may be at a competitive disadvantage that could delay the initiation, recruitment, timing, completion of our clinical trials and obtaining regulatory approvals, if at all, for our product candidate. We, and our collaborators, must comply with extensive government regulations in order to advance our product candidate through the development process and ultimately obtain and maintain marketing approval for our products in the U. S. and abroad. The product candidate that we, or our collaborators, are developing require regulatory approval to advance through clinical development and to ultimately be marketed and sold and are subject to extensive and rigorous domestic and foreign government regulation. In the U. S., the FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record- keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical and biopharmaceutical products. Our product candidate is also subject to similar regulation by foreign governments to the extent we seek to develop or market them in those countries. We, or our collaborators, must provide the FDA and foreign regulatory authorities, if applicable, with preclinical and clinical data, as well as data supporting an acceptable manufacturing process, that appropriately demonstrate our product candidates' safety and efficacy before they can be approved for the targeted indications. Our product candidate has not been approved for sale in the U. S. or any foreign market, and we cannot predict whether we or our collaborators will obtain regulatory approval for any product candidate we are developing or plan to develop. The regulatory review and approval process can take many years, is dependent upon the type, complexity, novelty of, and medical need for the product candidate, requires the expenditure of substantial resources, and involves post- marketing surveillance and vigilance and ongoing requirements for post- marketing studies or Phase 4 clinical trials. In addition, we or our collaborators may encounter delays in, or fail to gain, regulatory approval for our product candidate based upon additional governmental regulation resulting from future legislative, administrative action or changes in FDA' s or other similar foreign regulatory authorities' policy or interpretation during the period of product development. Delays or failures in obtaining regulatory approval to advance our product candidate through clinical development, and ultimately commercialize them, may: • adversely impact our ability to raise sufficient capital to fund the development of our product candidate; • adversely affect our ability to further develop or commercialize our product candidate; • diminish any competitive advantages that we or our collaborators may have or attain; and • adversely affect the receipt of potential milestone payments and royalties from the sale of our products or product revenues. Furthermore, any regulatory approvals, if granted, may later be withdrawn. If we or our collaborators fail to comply with applicable regulatory requirements at any time, or if post- approval safety concerns arise, we or our collaborators may be subject to restrictions or a number of actions, including: • delays, suspension or termination of clinical trials related to our products; • refusal by regulatory authorities to review pending applications or supplements to approved applications; • product recalls or seizures; • suspension of manufacturing; • withdrawals of previously approved marketing applications; and • fines, civil penalties and criminal prosecutions. Additionally, at any time we or our collaborators may voluntarily suspend or terminate the preclinical or clinical development of a product candidate, or withdraw any approved product from the market if we believe that it may pose an unacceptable safety risk to patients, or if the product candidate or approved product no longer meets our business objectives. The ability to develop or market a pharmaceutical product outside of the U. S. is contingent upon receiving appropriate authorization from the respective foreign regulatory authorities. Foreign regulatory approval processes typically include many, if not all, of the risks and requirements associated with the FDA regulatory process for drug development and may include additional risks. We have limited experience in the development of small molecule product candidates and therefore may encounter difficulties developing our product candidate or managing our operations in the future. Our product candidate, rencofilstat is a chemical compound, also referred to as small molecules. We have limited experience in the discovery, development and manufacturing of these small molecule antiviral compounds. In order to successfully develop these product candidates, we must continuously supplement our research, clinical development, regulatory, medicinal chemistry, virology and manufacturing capabilities through the addition of key employees, consultants or third- party contractors to provide certain capabilities and skill sets that we do not possess. Furthermore, we have adopted an operating model that largely relies on the outsourcing of several responsibilities and key activities to third- party consultants, and contract research and manufacturing organizations in order to advance the development of our product candidate. Therefore, our success depends in part on our ability to retain highly qualified key management personnel, and directors to develop, implement and execute our business strategy, operate the Company and oversee the activities of our consultants and contractors, as well as academic and corporate advisors or consultants to assist us in this regard. We are currently highly dependent upon the efforts of our management team. In order to develop our product candidate, we need to retain or attract certain personnel, consultants or advisors with experience in the drug development activities of small molecules that include a number of disciplines, including research and development, clinical trials, medical matters, government regulation of pharmaceuticals, manufacturing, formulation and chemistry, business development, accounting, finance, regulatory affairs, human resources and information systems. ~~We are highly dependent upon our senior management and scientific staff, particularly Dr. Robert Foster, our Chief Executive Officer. The loss of services of Dr. Foster or other members of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidate.~~ Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. The competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. While we have not had difficulties recruiting qualified individuals, to date, we may not be able to attract and retain quality personnel on acceptable terms given the competition for such personnel among

biotechnology, pharmaceutical and other companies. ~~Although we have not experienced material difficulties in retaining key~~ **In December 2023, the board of directors approved a strategic restructuring plan to preserve capital by reducing operating costs. This plan includes the reduction of** personnel in the **first quarter** ~~past, we may not be able to continue to do so in the future on acceptable terms, if at all. If we lose any key managers or employees or are unable to attract and retain qualified key personnel, directors, advisors or consultants, the development~~ of **2024** ~~our product candidate could be delayed or terminated, and our business may be harmed~~ . We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates or continue our development programs. We expect to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidate for which we receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidate. We may also seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects. Our future capital requirements will depend on many factors, including: • the progress of the development of our product candidates; • the number of product candidates we pursue; • the time and costs involved in obtaining regulatory approvals; • the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims; • our plans to establish sales, marketing and / or manufacturing capabilities; • the effect of competing technological and market developments; • the terms and timing of any collaborative, licensing and other arrangements that we may establish; • general market conditions for offerings from biopharmaceutical companies; • our ability to establish, enforce and maintain selected strategic alliances and activities required for product commercialization; and • our revenues, if any, from successful development and commercialization of our product candidates. In order to carry out our business plan and implement our strategy, we anticipate that we will need to obtain additional financing from time to time and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity- related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to certain of our product candidate or marketing territories. Our inability to raise capital when needed would harm our business, financial condition and results of operations, and could cause our stock price to decline or require that we wind down our operations altogether. We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business. A pharmaceutical product cannot be marketed in the U. S. or other countries until we have completed rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidate will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U. S. Patent and Trademark Office, or the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if the FDA believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidate. If we adopt an alternative brand name, we will lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidate. Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Our product candidate may not prove to be safe and efficacious in clinical trials and may not meet all the applicable regulatory requirements needed to receive regulatory approval. In order to receive regulatory approval for the commercialization of our product candidate, we must conduct, at our own expense, extensive preclinical testing and clinical trials to demonstrate safety and efficacy of our product candidate for the intended indication of use. Clinical testing is expensive, can take many years to complete, if at all, and its outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of new drugs do not necessarily predict the results of later- stage clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of our product candidate, and if those assumptions are incorrect, it may not produce statistically significant results. Preliminary results may not be confirmed on full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical trials may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidate may not be sufficient to support the filing of an NDA or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits. Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue. We may experience delays in clinical testing of our product candidate. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with

prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial ~~, related to the COVID- 19 pandemic~~ , or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, competing clinical trials and new drugs approved for the conditions we are investigating. Clinical investigators will need to decide whether to offer their patients enrollment in clinical trials of our product candidate versus treating these patients with commercially available drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development, timeliness and approval process and delay our ability to generate revenue. 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 candidate, 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. We have not obtained regulatory approval for any product candidate, and it is possible that our existing product candidate or any product candidate we may seek to develop in the future will ever obtain regulatory approval. Our product candidate could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; • the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of our product candidate may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere; • 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; • the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change 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 candidate, which would significantly harm our business, results of operations and prospects. In addition, even if we were to obtain approval, regulatory authorities may approve our product candidate 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 materially harm the commercial prospects for our product candidate. We have not previously submitted a biologics license application, or BLA, or a New Drug Application, or NDA, to the FDA, or similar drug approval filings to comparable foreign authorities, for our product candidate, and we cannot be certain that our product candidate will be successful in clinical trials or receive regulatory approval. Further, our product candidate may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidate, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market our product candidate, our revenues will be dependent, in part, upon our collaborators' ability to obtain regulatory approval of the companion diagnostics to be used with our product candidate, as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our product candidate are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved. We plan to seek regulatory approval and to commercialize our product candidate, directly or with a collaborator, worldwide including the United States, the European Union and other additional foreign countries which we have not yet identified. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidate, and we cannot predict success in these jurisdictions. We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidate. Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients. Administering any of our product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidate and could result in the FDA or other regulatory authorities denying further development or approval of our product candidate for any or all targeted indications. Ultimately, our product candidate may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials. If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected. As a developer of pharmaceuticals, even though we do not intend to make referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse, false claims and patients' privacy rights are and will be applicable

to our business. We could be subject to healthcare fraud and abuse laws and patient privacy laws of both the federal government and the states in which we conduct our business. The laws include: • the federal healthcare program anti- kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs; • federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third- party payers that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers; • the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; • the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug manufacturing and product marketing, prohibits manufacturers from marketing drug products for off- label use and regulates the distribution of drug samples; and • state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws which may apply to items or services reimbursed by any third- party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts. If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management' s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly. If we are unable to satisfy regulatory requirements, we may not be able to commercialize our product candidate. We need FDA approval prior to marketing our product candidate in the United States. If we fail to obtain FDA approval to market our product candidate, we will be unable to sell our product candidate in the United States and we will not generate any revenue. The FDA' s review and approval process, including among other things, evaluation of preclinical studies and clinical trials of a product candidate as well as the manufacturing process and facility, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well- designed and well- controlled pre-clinical testing and clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. Satisfaction of these requirements typically takes several years, and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we will submit an NDA for approval for our product candidate currently under development. Any approvals we may obtain may not cover all the clinical indications for which we are seeking approval or may contain significant limitations on the conditions of use. The FDA has substantial discretion in the NDA review process and may either refuse to file our NDA for substantive review or may decide that our data is insufficient to support approval of our product candidate for the claimed intended uses. Following any regulatory approval of our product candidate, we will be subject to continuing regulatory obligations such as safety reporting, required and additional post marketing obligations, and regulatory oversight of promotion and marketing. Even if we receive regulatory approvals, the FDA may subsequently seek to withdraw approval of our NDA if we determine that new data or a reevaluation of existing data show the product is unsafe for use under the conditions of use upon the basis of which the NDA was approved or based on new evidence of adverse effects or adverse clinical experience, or upon other new information. If the FDA does not file or approve our NDA or withdraws approval of our NDA, the FDA may require that we conduct additional clinical trials, preclinical or manufacturing studies and submit that data before it will reconsider our application. Depending on the extent of these or any other requested studies, approval of any applications that we submit may be delayed by several years, may require us to expend more resources than we have available, or may never be obtained at all. We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products to the extent we seek regulatory approval to develop and market our product candidate in a foreign jurisdiction. As of the date hereof we have not identified any foreign jurisdictions which we intend to seek approval from. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to marketing the product in those countries. The approval process varies, and the time needed to secure approval in any region such as the European Union or in a country with an independent review procedure may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that an approval in one country or region will result in approval elsewhere. If our product candidate is unable to compete effectively with marketed drugs targeting similar indications as our product candidate, our commercial opportunity will be reduced or eliminated. We face competition generally from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Small or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize any drugs that are safer, more effective, have fewer side effects or are less expensive than our product candidate. These potential competitors compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring technologies and technology licenses complementary to our

programs or advantageous to our business. If approved and commercialized, rencofilstat intends to compete with at numerous therapies for the treatment of NASH that are currently in development. To our knowledge, other potential competitors are in both later and earlier stages of development. If potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for rencofilstat. We expect that our ability to compete effectively will depend upon our ability to: • successfully identify and develop key points of product differentiations from currently available therapies; • successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost- effective manner; • maintain a proprietary position for our products and manufacturing processes and other related product technology; • attract and retain key personnel; • develop relationships with physicians prescribing these products; and • build an adequate sales and marketing infrastructure for our product candidate. Because we will be competing against significantly larger companies with established track records, we will have to demonstrate that, based on experience, clinical data, side- effect profiles and other factors, our products, if approved, are competitive with other products. If we are unable to compete effectively and differentiate our products from other marketed shingles drugs, we may never generate meaningful revenue. We currently have no sales and marketing organization. If we are unable to establish a direct sales force in the United States to promote our products, the commercial opportunity for our products may be diminished. We currently have no sales and marketing organization. We will incur significant additional expenses and commit significant additional management resources to establish our sales force. We may not be able to establish these capabilities despite these additional expenditures. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire and train sales and marketing personnel. If we elect to rely on third parties to sell our product candidate in the United States, we may receive less revenue than if we sold our products directly. In addition, although we would intend to use due diligence in monitoring their activities, we may have little or no control over the sales efforts of those third parties. In the event we are unable to develop our own sales force or collaborate with a third party to sell our product candidate, we may not be able to commercialize our product candidate which would negatively impact our ability to generate revenue. We may need others to market and commercialize our product candidate in international markets. In the future, if appropriate regulatory approvals are obtained, we may commercialize our product candidate in international markets. However, we have not decided how to commercialize our product candidates in those markets. We may decide to build our own sales force or sell our products through third parties. If we decide to sell our product candidates in international markets through a third party, we may not be able to enter into any marketing arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into a marketing arrangement for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited. If the manufacturers upon whom we rely fail to produce our product candidates, in the volumes that we require on a timely basis or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of our product candidate. We do not currently possess internal manufacturing capacity. We plan to utilize the services of contract manufacturers to manufacture our clinical supplies. Any curtailment in the availability of rencofilstat, however, could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs. We continue to pursue active pharmaceutical ingredients, or API, and drug product supply agreements with other manufacturers. We may be required to agree to minimum volume requirements, exclusivity arrangements or other restrictions with the contract manufacturers. We may not be able to enter into long- term agreements on commercially reasonable terms, or at all. If we change or add manufacturers, the FDA and comparable foreign regulators may require approval of the changes. Approval of these changes could require new testing by the manufacturer and compliance inspections to ensure the manufacturer is conforming to all applicable laws and regulations and good manufacturing practices or GMP. In addition, the new manufacturers would have to be educated in or independently develop the processes necessary to produce our product candidate. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products may encounter difficulties in production, particularly in scaling up production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or to terminate a clinical trial. We are responsible for ensuring that each of our contract manufacturers comply with the GMP requirements of the FDA and other regulatory authorities from which we seek to obtain product approval. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The approval process for NDAs includes a review of the manufacturer’ s compliance with GMP requirements. We are responsible for regularly assessing a contract manufacturer’ s compliance with GMP requirements through record reviews and periodic audits and for ensuring that the contract manufacturer takes responsibility and corrective action for any identified deviations. Manufacturers our product candidates may be unable to comply with these GMP requirements and with other FDA and foreign regulatory requirements, if any. While we will oversee compliance by our contract manufacturers, ultimately, we will not have control over our manufacturers’ compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety our product candidates is compromised due to a manufacturers’ failure to adhere to applicable laws or for other reasons, we may

not be able to obtain regulatory approval for or successfully commercialize our product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our product candidates, entail higher costs or result in us being unable to effectively commercialize our product candidates. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for any approved products and would lose potential revenues. We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates. To date, our product candidates have been manufactured in small quantities for preclinical studies and clinical trials. If our any of our product candidates are approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidates in larger quantities. We may not be able to successfully increase the manufacturing capacity for our product candidates in a timely or economic manner, or at all. Significant scale- up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for a product candidate, the clinical trials as well as the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates require precise, high- quality manufacturing. Our failure to achieve and maintain these high- quality manufacturing standards in collaboration with our third- party manufacturers, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations. Materials necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates. We rely on the third- party manufacturers of our product candidates to purchase from third- party suppliers the materials necessary to produce bulk APIs, and product candidates for our clinical trials, and we will rely on such manufacturers to purchase such materials to produce the APIs and finished products for any commercial distribution of our products if we obtain marketing approval. Suppliers may not sell these materials to our manufacturers at the time they need them in order to meet our required delivery schedule or on commercially reasonable terms, if at all. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements to produce these materials. If our manufacturers are unable to obtain these materials for our clinical trials, testing of the affected product candidates would be delayed, which may significantly impact our ability to develop the product candidates. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for one of our products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm our ability to generate revenues from such product and achieve or sustain profitability. Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues. If any of our product candidates is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third- party payers and our profitability and growth will depend on several factors, including: • demonstration of safety and efficacy; • changes in the practice guidelines and the standard of care for the targeted indication; • relative convenience and ease of administration; • the prevalence and severity of any adverse side effects; • budget impact of adoption of our product on relevant drug formularies and the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs; • pricing, reimbursement and cost effectiveness, which may be subject to regulatory control; • effectiveness of our or any of our partners' sales and marketing strategies; • the product labeling or product insert required by the FDA or regulatory authority in other countries; and • the availability of adequate third- party insurance coverage or reimbursement. If any product candidates that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidates, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost- effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third- party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third- party payers, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third- party payers on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful. Guidelines and recommendations published by various organizations can impact the use of our product. Government agencies promulgate regulations and guidelines directly applicable to us and to our product. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our proposed product. If third- party contract manufacturers upon whom we rely to formulate and manufacture our product candidate do not perform, fail to manufacture according to our specifications or fail to comply with strict regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidates could be delayed or terminated or we could incur significant additional expenses. We do not own or operate any manufacturing facilities. We intend to rely on third- party contractors, at least for the foreseeable future, to formulate and manufacture these preclinical and clinical materials. Our reliance on third- party contract manufacturers expose us to a number of risks, any of which could delay or prevent the completion of our preclinical studies or clinical trials, or the regulatory approval or commercialization of our product candidate, result in higher costs, or deprive us of potential product revenues. Some of these

risks include: • our third- party contractors failing to develop an acceptable formulation to support later- stage clinical trials for, or the commercialization of, our product candidate; • our contract manufacturers failing to manufacture our product candidates according to their own standards, our specifications, cGMPs, or otherwise manufacturing material that we or the FDA may deem to be unsuitable in our clinical trials; • our contract manufacturers being unable to increase the scale of, increase the capacity for, or reformulate the form of our product candidates. We may experience a shortage in supply, or the cost to manufacture our products may increase to the point where it adversely affects the cost of our product candidate. We cannot assure you that our contract manufacturers will be able to manufacture our products at a suitable scale, or we will be able to find alternative manufacturers acceptable to us that can do so; • our contract manufacturers placing a priority on the manufacture of their own products, or other customers' products; • our contract manufacturers failing to perform as agreed or not remain in the contract manufacturing business; and • our contract manufacturers' plants being closed as a result of regulatory sanctions or a natural disaster. Manufacturers of pharmaceutical products are subject to ongoing periodic inspections by the FDA, the U. S. Drug Enforcement Administration (" DEA ") and corresponding state and foreign agencies to ensure strict compliance with FDA-mandated current good marketing practices or cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit their performance, we do not have control over our third- party contract manufacturers' compliance with these regulations and standards. Failure by our third- party manufacturers, or us, to comply with applicable regulations could result in sanctions being imposed on us or the drug manufacturer from the production of other third- party products. These sanctions may include fines, injunctions, civil penalties, failure of the government to grant pre- market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In the event that we need to change our third-party contract manufacturers, our preclinical studies, clinical trials or the commercialization of our product candidate could be delayed, adversely affected or terminated, or such a change may result in significantly higher costs. Due to regulatory restrictions inherent in an IND, NDA or BLA, various steps in the manufacture of our product candidate may need to be sole-sourced. In accordance with cGMPs, changing manufacturers may require the re- validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our current or future contract manufacturers may be difficult for us and could be costly, which could result in our inability to manufacture our product candidate for an extended period of time and therefore a delay in the development of our product candidate. Further, in order to maintain our development time lines in the event of a change in our third- party contract manufacturer, we may incur significantly higher costs to manufacture our product candidate. Our industry is highly competitive and subject to rapid technological changes. As a result, we may be unable to compete successfully or develop innovative products, which could harm our business. Our industry is highly competitive and characterized by rapid technological change. Key competitive factors in our industry include, among others, the ability to successfully advance the development of a product candidate through preclinical and clinical trials; the efficacy, toxicological, safety, resistance or cross-resistance, and dosing profile of a product or product candidate; the timing and scope of regulatory approvals, if ever achieved; reimbursement rates for and the average selling price of competing products and pharmaceutical products in general; the availability of raw materials and qualified contract manufacturing and manufacturing capacity; manufacturing costs; establishing and maintaining intellectual property and patent rights and their protection; and sales and marketing capabilities. If ultimately approved, rencofilstat or any other product candidate we may develop, would compete against existing therapies or other product candidate in various stages of clinical development that we believe may potentially become available in the future. Developing a pharmaceutical product candidate is a highly competitive, expensive and risky activity with a long business cycle. Many organizations, including the large pharmaceutical and biopharmaceutical companies that have existing products on the market or in clinical development that could compete with our product candidate have substantially more resources than we have, and much greater capabilities and experience than we have in research and discovery, designing and conducting preclinical studies and clinical trials, operating in a highly regulated environment, manufacturing drug substances and drug products, and marketing and sales. Our competitors may be more successful than we are in obtaining FDA or other regulatory approvals for their product candidates and achieving broad market acceptance once they are approved. Our competitors' drugs or product candidates may be more effective, have fewer negative side effects, be more convenient to administer, have a more favorable resistance profile, or be more effectively marketed and sold than any drug we, or our potential collaborators, may develop or commercialize. New drugs or classes of drugs from competitors may render our product candidate obsolete or non- competitive before we are able to successfully develop them or, if approved, before we can recover the expenses of developing and commercializing them. We anticipate that we or our collaborators will face intense and increasing competition as new drugs and drug classes enter the market and advanced technologies or new drug targets become available. If our product candidate does not demonstrate any competitive advantages over existing drugs, new drugs or product candidate, we or our future collaborators may terminate the development or commercialization of our product candidate at any time. We anticipate that our product candidate if successfully developed and approved, will compete directly or indirectly with existing drugs, some of which are generic. Generic drugs are drugs whose patent protection has expired, and generally have an average selling price substantially lower than drugs protected by intellectual property rights. Unless a patented drug can differentiate itself from a generic drug in a meaningful manner, the existence of generic competition in any indication may impose significant pricing pressure on competing patented drugs. We also face, and will continue to face, intense competition from other companies for collaborative arrangements with pharmaceutical and biopharmaceutical companies, and for attracting investigators and clinical sites capable of conducting our preclinical studies and clinical trials. These competitors, either alone or with their collaborators, may succeed in developing technologies or products that are safer, more effective, less expensive or easier to administer than ours. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals for their product candidates more rapidly than we can. Companies that can complete clinical trials, obtain required regulatory approvals and commercialize their

products before their competitors may achieve a significant competitive advantage, including certain patent and FDA marketing exclusivity rights that could delay the ability of competitors to market certain products. We cannot assure you that product candidates resulting from our research and development efforts, or from joint efforts with our collaborators, will be able to compete successfully with our competitors' existing products or products under development. We do not currently have any internal drug discovery capabilities, and therefore we are dependent on in- licensing or acquiring development programs from third parties in order to obtain additional product candidates. If in the future we decide to further expand our pipeline, we will be dependent on in- licensing or acquiring product candidates as we do not have significant internal discovery capabilities at this time. Accordingly, in order to generate and expand our development pipeline, we have relied, and will continue to rely, on obtaining discoveries, new technologies, intellectual property and product candidates from third parties through sponsored research, in- licensing arrangements or acquisitions. We may face substantial competition from other biotechnology and pharmaceutical companies, many of which may have greater resources then we have, in obtaining these in- licensing, sponsored research or acquisition opportunities. Additional in- licensing or acquisition opportunities may not be available to us on terms we find acceptable, if at all. In- licensed compounds that appear promising in research or in preclinical studies may fail to progress into further preclinical studies or clinical trials. If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business. The use of any of our existing or future product candidate in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently have product liability insurance coverage for our clinical trials in the amount of $ 10. 0 million. Such insurance coverage may not protect us against any or all the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event our product candidate is approved for sale by the FDA and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business. If our use of hazardous materials results in contamination or injury, we could suffer significant financial loss. Our research activities, through third parties, involve the controlled use of certain hazardous materials and medical waste. Notwithstanding the regulations controlling the use and disposal of these materials, as well as the safety procedures we undertake, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge or exposure, we may be held liable for any resulting damages, which may exceed our financial resources and have an adverse effect on our business. Our operations could be disrupted if our information systems fail, if we are unsuccessful in implementing necessary upgrades or if we are subject to cyber- attacks. Our business depends on the efficient and uninterrupted operation of our computer and communications systems and networks, hardware and software systems and our other information technology. We collect and maintain information, which includes confidential and proprietary information as well as personal information regarding our collaborators and employees, in digital form. Data maintained in digital form is subject to risk of malware, computer viruses, computer hacking, acts of data theft, phishing, other cyber- attacks and employee error or malfeasance, which are increasing in frequency and sophistication. In July 2019, one of our employees was victim to a phishing incident, to which we have taken certain actions in response to and to which we do not anticipate significant disruption to our business or future prospects. Despite our efforts to monitor and safeguard our systems to prevent data compromise, the possibility of data compromise cannot be eliminated entirely, and risks associated with intrusion, tampering, and theft remain. In addition, we may not have sufficient insurance coverage with respect to system failures or cyber- attacks. A failure of our systems, or an inability to successfully expand the capacity of these systems, or an inability to successfully integrate new technologies into our existing systems could have a material adverse effect on our business, results of operations, financial condition, and cash flows. Business disruptions could seriously harm future revenue and financial condition and increase our costs and expenses. Our operations, and those of our third- party manufacturers, CROs and other contractors and consultants, could be subject to pandemics ~~(including the COVID- 19 pandemic)~~ , earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man- made disasters or business interruptions, for which we are predominantly self- insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third- party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Any disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business. The occurrence of regional epidemics or a global ~~pandemic, such as the COVID- 19~~ pandemic, have had and may continue to have an adverse effect on how we and our CROs, CMOs, and other contractors, consultants and third parties are operating our businesses and our operating results. Our operations have also been and may in the future be negatively affected by a range of external factors related to the pandemic that are not within our control, including the emergence and spread of more transmissible variants. The extent to which global pandemics, such as the COVID- 19 pandemic, impact our financial condition or results of operations will depend on factors such as the duration and scope of the pandemic, as well as whether there is a material impact on the businesses of our CROs, CMOs, and other contractors, consultants and third parties. To the extent that the pandemic harms our business and results of operations, many of the other risks described in this Part I, Item 1A of this report may be heightened. In addition, we rely on a third- party manufacturer to

manufacture API for our product candidate. Any disruption in production or inability of our manufacturer to produce or ship adequate quantities to meet our needs, whether as a result of a natural disaster or other causes (such as the COVID- 19 pandemic), could impair our ability to operate our business on a day- to- day basis and to continue our research and development of our product candidate. In addition, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or political unrest in areas in which we do business. Any recall of the manufacturing lots or similar action regarding our API used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third- party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidate and impair our competitive position. Our approach to the discovery and development of product candidates based on AI- POWR ™ is novel and unproven, and we do not know whether we will be able to develop any products of commercial value. We intend to leverage AI- POWR ™ to potentially identify novel indications for rencofilstat and possibly identify new targets and new drug molecules to broaden our pipeline for patients whose diseases have not been adequately addressed to date by other approaches and to design and conduct efficient clinical trials with a higher likelihood of success. While we believe that applying AI- POWR ™ to create medicines for defined patient populations may potentially enable drug research and clinical development that is more efficient than conventional drug research and development, our approach is both novel and unproven. Because our approach is both novel and unproven, the cost and time needed to develop our product candidate is difficult to predict, and our efforts may not result in the discovery and development of commercially viable medicines. We may also be incorrect about the effects of our product candidate on the diseases of our defined patient populations, which may limit the utility of our approach or the perception of the utility of our approach. Furthermore, our estimates of our defined patient populations available for study and treatment may be lower than expected, which could adversely affect our ability to conduct clinical trials and may also adversely affect the size of any market for medicines we may successfully commercialize. Our approach may not result in time savings, higher success rates or reduced costs as we expect it to, and if not, we may not attract collaborators or develop new drugs as quickly or cost effectively as expected and therefore we may not be able to commercialize our approach as originally expected. AI- POWR ™ may fail to help us discover and / or develop additional potential product candidates. Any drug discovery that we are conducting using AI- POWR ™ may not be successful in identifying compounds that have commercial value or therapeutic utility. AI- POWR ™ may initially show promise in identifying potential product candidates, yet fail to yield viable product candidates for clinical development or commercialization for a number of reasons, including: • research programs to identify new product candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new product candidates. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price; • compounds found through AI- POWR ™ may not demonstrate efficacy, safety or tolerability; • potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance; • competitors may develop alternative therapies that render our potential product candidates non- competitive or less attractive; or • a potential product candidate may not be capable of being produced at an acceptable cost. Risks Relating to the Commercialization of our Product Candidate. We may delay or terminate the development of our product candidate at any time if we believe the perceived market or commercial opportunity does not justify further investment, which could materially harm our business. Even though the results of preclinical studies and clinical trials that we have conducted or may conduct in the future may support further development of our product candidate, we may delay, suspend or terminate the future development of our product candidate at any time for strategic, business, financial or other reasons, including the determination or belief that the emerging profile of the product candidate is such that it may not receive FDA approval, gain meaningful market acceptance, generate a significant return to shareholders, or otherwise provide any competitive advantages in its intended indication or market. If we fail to enter into collaborations, license agreements or other transactions with third parties to accelerate the development of our product candidate, we will bear the risk of developmental failure. We plan to seek out- licensing opportunities as a way to accelerate the development of our product candidate. There is no guarantee that we will enter into a future transaction on favorable terms, or at all, or that discussions will initiate or progress on our desired timelines. Completing transactions of this nature is difficult and time- consuming. Potentially interested parties may decline to re- engage or may terminate discussions based upon their assessment of our competitive, financial, regulatory or intellectual property position or for any other reason. Furthermore, we may choose to defer consummating a transaction relating to our product candidate until additional clinical data are obtained. If we decide to not actively pursue a transaction until we have additional clinical data, we and our stockholders will bear the risk that our product candidate fails prior to any future transaction. If we fail to enter into or maintain collaborations or other sales, marketing and distribution arrangements with third parties to commercialize our product candidate, or otherwise fail to establish marketing and sales capabilities, we may not be able to successfully commercialize our products. We currently have no infrastructure to support the commercialization of our product candidate, and have little, if any, experience in the commercialization of pharmaceutical products. Therefore, if our product candidate is successfully developed and ultimately approved for sale, our future profitability will depend largely on our ability to access or develop suitable marketing and sales capabilities. We anticipate that we will need to establish relationships with other companies, through license and collaborations agreements, to commercialize our product candidate in the U. S. and in other countries around the world. To the extent that we enter into these license and collaboration agreements, or marketing and sales arrangements with other companies to sell, promote or market our products in the U. S. or abroad, our product revenues, which may be in the form of indirect revenue, a royalty, or a split of profits, will depend largely on their efforts, which may not be successful. In the event we

develop a sales force and marketing capabilities, this may result in us incurring significant costs before the time that we may generate any significant product revenues. We may not be able to attract and retain qualified third parties or marketing or sales personnel or be able to establish marketing capabilities or an effective sales force. If government and third- party payers fail to provide adequate reimbursement or coverage for our products or those we develop through collaborations, our revenues and potential for profitability will be harmed. In the U. S. and most foreign markets, our product revenues, and therefore the inherent value of our product candidate, will depend largely upon the reimbursement rates established by third- party payers for such product candidate or products. Such third- party payers include government health administration authorities, managed- care organizations, private health insurers and other similar organizations. These third- party payers are increasingly challenging the price and examining the cost effectiveness of medical products, services and pharmaceuticals. In addition, significant uncertainty exists as to the reimbursement status, if any, of newly approved drugs or pharmaceutical products. Further, the comparative effectiveness of new compounds over existing therapies and the assessment of other non- clinical outcomes are increasingly being considered in the decision by these payers to establish reimbursement rates. We may also need to conduct post- marketing clinical trials in order to demonstrate the cost- effectiveness of our products. Such studies may require us to commit a significant amount of management time and financial resources. We cannot assure you that any products we successfully develop will be reimbursed in part, or at all, by any third- party payers in any countries. Domestic and foreign governments continue to propose legislation designed to expand the coverage, yet reduce the cost, of healthcare, including pharmaceutical drugs. In some foreign markets, governmental agencies control prescription drugs' pricing and profitability. In the U. S. significant changes in federal health care policy have been recently approved and will mostly likely result in reduced reimbursement rates in the future. We expect that there will continue to be federal and state proposals to implement more governmental control over reimbursement rates of pharmaceutical products. In addition, we expect that increasing emphasis on managed care and government intervention in the U. S. healthcare system will continue to put downward pressure on the pricing of pharmaceutical products domestically. Cost control initiatives could decrease the price that we receive for our product candidate that may be approved for sale in the future, which would limit our revenues and profitability. Accordingly, legislation and regulations affecting the pricing of pharmaceutical products may change before our product candidate is approved for sale, which could further limit or eliminate reimbursement rates for our product candidate. If any product candidate that we develop independently or through collaborations is approved but does not gain meaningful acceptance in its intended market, we are not likely to generate significant revenues or become profitable. Even if our product candidate is successfully developed and we or a collaborator obtain the requisite regulatory approvals to commercialize it in the future, it may not gain market acceptance or utilization among physicians, patients or third- party payers. The degree of market acceptance that our product candidate may achieve will depend on several factors, including: • the therapeutic efficacy or perceived benefit of the product relative to existing therapies, if they exist; • the timing of market approval and existing market for competitive drugs; • the level of reimbursement provided by payers to cover the cost of the product to patients; • the net cost of the product to the user or payer; • the convenience and ease of administration of our product; • the product' s potential advantages over existing or alternative therapies; • the actual or perceived safety of similar classes of products; • the actual or perceived existence, prevalence and severity of negative side effects; • the effectiveness of sales, marketing and distribution capabilities; and • the scope of the product label approved by the FDA. There can be no assurance that physicians will choose to prescribe or administer our product, if approved, to the intended patient population. If our product does not achieve meaningful market acceptance, or if the market for our product proves to be smaller than anticipated, we may not generate significant revenues or ever become profitable. Even if we or a collaborator achieve market acceptance for our product, we may experience downward pricing pressure on the price of our product due to social or political pressure to lower the cost of drugs, which would reduce our revenue and future profitability. Pressure from social activist groups and future government regulations, whose goal it is to reduce the cost of drugs, particularly in less developed nations, also may put downward pressure on the price of drugs, which could result in downward pressure on the prices of our product in the future. We may be unable to successfully develop a product candidate that is the subject of collaboration if our collaborator does not perform, terminates our agreement, or delays the development of our product candidate. We expect to continue to enter into and rely on license and collaboration agreements or other business arrangements with third parties to further develop and / or commercialize our existing and future product candidates. Such collaborators or partners may not perform as agreed upon or anticipated, fail to comply with strict regulations, or elect to delay or terminate their efforts in developing or commercializing our product candidates even though we have met our obligations under the arrangement. For example, if an existing or future collaborator does not devote sufficient time and resources to our collaboration arrangement, we may not realize the full potential benefits of the arrangement, and our results of operations may be adversely affected. A majority of the potential revenue from existing and future collaborations will likely consist of contingent payments, such as payments for achieving development or regulatory milestones and royalties payable on the sales of approved products. The milestone and royalty revenues that we may receive under these collaborations will depend primarily upon our collaborator' s ability to successfully develop and commercialize our product candidate. In addition, our collaborators may decide to enter into arrangements with third parties to commercialize products developed under our existing or future collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. In many cases, we will not be directly involved in the development or commercialization of our product candidate and, accordingly, will depend entirely on our collaborators. Our collaboration partners may fail to develop or effectively commercialize our product candidates because they: • do not allocate the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited capital resources, or the belief that other product candidates or other internal programs may have a higher likelihood of obtaining regulatory approval or may potentially generate a greater return on investment; • do not have sufficient resources necessary to fully support the product candidates through clinical development, regulatory approval and commercialization; • are unable to obtain the necessary regulatory approvals; or • may re-

evaluate the importance and their support for developing our product candidate pipeline due to a change in management, business operations or financial strategy. In addition, a collaborator may decide to pursue the development of a competitive product candidate developed outside of our collaboration with them. Conflicts may also arise if there is a dispute about the progress of, or other activities related to, the clinical development or commercialization of a product candidate, the achievement and payment of a milestone amount, the ownership of intellectual property that is developed during the course of the collaborative arrangement, or other licensing agreement terms. If a collaboration partner fails to develop or effectively commercialize our product candidate for any of these reasons, we may not be able to replace them with another partner willing to develop and commercialize our product candidate under similar terms, if at all. Similarly, we may disagree with a collaborator as to which party owns newly or jointly developed intellectual property. Should an agreement be revised or terminated as a result of a dispute and before we have realized the anticipated benefits of the collaboration, we may not be able to obtain certain development support or revenues that we anticipated receiving. We may also be unable to obtain, on terms acceptable to us, a license from such collaboration partner to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize the product candidate. Risks Related to Our Intellectual Property If we are unable to adequately protect or expand our intellectual property related to our current or future product candidates, our business prospects could be harmed. Our success, competitive position and future revenues will depend in part on our ability to obtain and maintain patent protection for our product candidates, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We will be able to protect our proprietary intellectual property rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of pharmaceutical and biopharmaceutical companies involves complex legal and factual questions, and, therefore, we cannot predict with certainty whether we will be able to ultimately enforce our patents or proprietary rights. Therefore, any issued patents that we own or otherwise have intellectual property rights to may be challenged, invalidated or circumvented, and may not provide us with the protection against competitors that we anticipate. The degree of future protection for our proprietary intellectual property rights is uncertain because issued patents and other legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Our future patent position will be influenced by the following factors: • we or our licensors may not have been the first to discover the inventions covered by each of our or our licensors' pending patent applications and issued patents, and we may have to engage in expensive and protracted interference proceedings to determine priority of invention; • our or our licensors' pending patent applications may not result in issued patents; • our or our licensors' issued patents may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties; and • third parties may develop intellectual property around our or our licensors' patent claims to design competitive intellectual property and ultimately product candidates that fall outside the scope of our or our licensors' patents. Because of the extensive time required for the development, testing and regulatory review and approval of a product candidate, it is possible that before our product candidate can be approved for sale and commercialized, our relevant patent rights may expire, or such patent rights may remain in force for only a short period following approval and commercialization. Patent expiration could adversely affect our ability to protect future product development and, consequently, our operating results and financial position. Also, patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the U. S. and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, we may not be able to prevent a third party from infringing our patents in a country that does not recognize or enforce patent rights, or that imposes compulsory licenses on or restricts the prices of life- saving drugs. Changes in either patent laws or in interpretations of patent laws in the U. S. and other countries may diminish the value of our intellectual property. We may not develop or obtain rights to products or processes that are patentable. Even if we or our licensors do obtain patents, such patents may not adequately protect the products or technologies we own or have licensed, or otherwise be limited in scope. In addition, we may not have total control over the patent prosecution of subject matter that we license from others. Accordingly, we may be unable to exercise the same degree of control over this intellectual property as we would over our own. Others may challenge, seek to invalidate, infringe or circumvent any pending or issued patents we own or license, and rights we receive under those issued patents may not provide competitive advantages to us. We cannot assure you as to the degree of protection that will be afforded by any of our issued or pending patents, or those licensed by us. If a third party claims we are infringing on its intellectual property rights, we could incur significant expenses, or be prevented from further developing or commercializing our product candidate. Our success will also depend on our ability to operate without infringing the patents and other proprietary intellectual property rights of third parties. This is generally referred to as having the " freedom to operate ". The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property claims, United States Patent and Trademark Office, or USPTO, interference proceedings and related legal and administrative proceedings, both in the U. S. and internationally, involve complex legal and factual questions. As a result, such proceedings are lengthy, costly and time- consuming and their outcome is highly uncertain. We may become involved in protracted and expensive litigation in order to determine the enforceability, scope and validity of the proprietary rights of others, or to determine whether we have the freedom to operate with respect to the intellectual property rights of others. Patent applications in the U. S. are, in most cases, maintained in secrecy until approximately 18 months after the patent application is filed. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to products similar to our product candidate may have already been filed by others without our knowledge. In the event that a third party has also filed a patent application covering our product candidate or other claims, we may have to participate in an adversarial proceeding,

known as an interference proceeding in the USPT office, or similar proceedings in other countries to determine the priority of invention. In the event an infringement claim is brought against us, we may be required to pay substantial legal fees and other expenses to defend such a claim and, if we are unsuccessful in defending the claim, we may be prevented from pursuing the development and commercialization of a product candidate and may be subject to injunctions and / or damage awards. In the future, the USPTO or a foreign patent office may grant patent rights to our product candidate or other claims to third parties. Subject to the issuance of these future patents, the claims of which will be unknown until issued, we may need to obtain a license or sublicense to these rights in order to have the appropriate freedom to further develop or commercialize them. Any required licenses may not be available to us on acceptable terms, if at all. If we need to obtain such licenses or sublicenses, but are unable to do so, we could encounter delays in the development of our product candidate, or be prevented from developing, manufacturing and commercializing our product candidate at all. If it is determined that we have infringed an issued patent and do not have the freedom to operate, we could be subject to injunctions, and / or compelled to pay significant damages, including punitive damages. In cases where we have in- licensed intellectual property, our failure to comply with the terms and conditions of such agreements could harm our business. It is becoming common for third parties to challenge patent claims on any successful product candidate or approved drug. If we or our collaborators become involved in any patent litigation, interference or other legal proceedings, we could incur substantial expense, and the efforts of our technical and management personnel will be significantly diverted. A negative outcome of such litigation or proceedings may expose us to the loss of our proprietary position or to significant liabilities or require us to seek licenses that may not be available from third parties on commercially acceptable terms, if at all. We may be restricted or prevented from developing, manufacturing and selling our product candidate in the event of an adverse determination in a judicial or administrative proceeding, or if we fail to obtain necessary licenses. We cannot be sure that any patents will be issued or that patents licensed to us will be issued from any of our patent applications or, should any patents issue, that we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that patents issued or licensed to us will be of any commercial value, or that private parties or competitors will not successfully challenge these patents or circumvent our patent position in the U. S. or abroad. In the absence of adequate patent protection, our business may be adversely affected by competitors who develop comparable technology or products. Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property. We rely on trade secrets to protect our technology, especially where we do not believe patent protection is obtainable, or prior to us filing patent applications on inventions we may make from time to time. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case, we could not assert any trade secret rights against such party. Enforcing a claim that a third- party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U. S. may be less willing to protect trade secrets. Costly and time- consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. Our failure to successfully discover, acquire, develop and market additional product candidates or approved products would impair our ability to grow. As part of our growth strategy, we intend to develop and market additional products and product candidates. We are pursuing various therapeutic opportunities through our pipeline. We may spend several years completing our development of any current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products. Failure of this strategy would impair our ability to grow. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in- licensing of third- party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in- licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all. In addition, future acquisitions may entail numerous operational and financial risks, including: • disruption of our business and diversion of our management' s time and attention to develop acquired products or technologies; • incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions; • higher than expected acquisition and integration costs; • difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel; • increased amortization expenses; • impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; • inability to motivate key employees of any acquired businesses; and • assumption of known and unknown liabilities. Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. Risks Related to Government Regulation Even if our

product candidate receives regulatory approval, it may still face future development and regulatory difficulties. Even if U. S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product' s indicated uses or impose ongoing requirements for potentially costly post- approval studies. Our product candidates would also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post- market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturer, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidate or the manufacturing facilities for our product candidate fail to comply with applicable regulatory requirements, a regulatory agency may: • issue warning letters; • impose civil or criminal penalties; • suspend regulatory approval; • suspend any ongoing clinical trials; • refuse to approve pending applications or supplements to applications filed by us; • impose restrictions on operations, including costly new manufacturing requirements; • seize or detain products or request us to initiate a product recall; or • pursue and obtain an injunction. Even if our product candidate receives regulatory approval in the United States, we may never receive approval to commercialize it outside of the United States. In the future, we may seek to commercialize our product candidate in foreign countries outside of the United States. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than, those in the United States. The time required to obtain approval in other jurisdictions might differ from that required to obtain FDA approval. The regulatory approval process in other jurisdictions may include all the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory processes in others. Failure to obtain regulatory approvals in other jurisdictions or any delay or setback in obtaining such approvals could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that our product candidates may not be approved for all indications for use included in proposed labeling or for any indications at all, which could limit the uses of our product candidate and have an adverse effect on our products' commercial potential or require costly post- marketing studies. We intend to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to seek or obtain regulatory approval for or commercialize our product candidate. We intend to enter into agreements with third- party contract research organizations, or CROs, under which we will delegate to the CROs the responsibility to coordinate and monitor the conduct of our clinical trials and to manage data for our clinical programs. We, our CROs and our clinical sites are required to comply with current Good Clinical Practices, or cGCPs, regulations and guidelines issued by the FDA and by similar governmental authorities in other countries where we are conducting clinical trials. We have an ongoing obligation to monitor the activities conducted by our CROs and at our clinical sites to confirm compliance with these requirements. In the future, if we, our CROs or our clinical sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations and will require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. 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 their 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 candidate. As a result, our financial results and the commercial prospects for our product candidate would be harmed, our costs could increase, and our ability to generate revenue could be delayed. We will need to increase the size of our organization. We are a small company with ~~25~~ **22** employees as of December 31, ~~2022~~ **2023 . In December 2023, our board of directors approved a strategic restructuring plan to preserve capital by reducing operating costs, which included a reduction in force** . To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees ~~. Over the next 12 months depending on the progress of our planned clinical trials and capital raising efforts, we plan to add additional employees to assist us with our clinical programs~~ . Our future financial performance and our ability to commercialize our product candidate and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to: • manage development efforts effectively; • manage our clinical trials effectively; • integrate additional management, administrative, manufacturing and sales and marketing personnel; • maintain sufficient administrative, accounting and management information systems and controls; and • hire and train additional qualified personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results and impact our ability to achieve development milestones. Reimbursement may not be available for our product candidate, which would impede sales. Market acceptance and sales of our product candidate may depend on coverage and reimbursement policies and health care reform measures. Decisions about formulary coverage as well as levels at which government authorities and third- party payers, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our products as well as levels at which these payers pay directly for our products, where applicable, could affect whether we are able to commercialize these products. We cannot be sure that reimbursement will be available for any of these products. Also, we cannot be sure that coverage or reimbursement amounts will not reduce the

demand for, or the price of, our products. We have not commenced efforts to have our product candidate reimbursed by government or third- party payers. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to commercialize our products. In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subjects the price of our products to governmental control, we may not be able to generate revenue, attain profitability or commercialize our products. As a result of legislative proposals and the trend towards managed health care in the United States, third- party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also impose strict prior authorization requirements and / or refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third- party payers will reimburse patients for their use of newly- approved drugs, which in turn will put pressure on the pricing of drugs. Healthcare reform measures and other recent legislative initiatives could adversely affect our business. The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third- party payors to contain or reduce the costs of health care and to lower drug prices. In the United States, comprehensive health care reform legislation has been enacted by the Federal government and we expect that there will continue to be a number of federal and state proposals to implement government control over the pricing of prescription pharmaceuticals. In addition, increasing emphasis on reducing the cost of health care in the United States will continue to put pressure on the pricing and reimbursement of prescription pharmaceuticals. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is already subject to government control. Additionally, other federal and state legislation impose obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the drug product provided to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding distribution of the drug product. Further, under this legislation, manufacturers will have drug product investigation, quarantine, disposition, notification and purchaser license verification responsibilities related to counterfeit, diverted, stolen and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Additionally, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was signed into law, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our drug products and potential drug candidates are: • an annual, nondeductible fee on any entity that manufactures, or imports, specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs; • an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23. 1 % and 13. 0 % of the average manufacturer price for branded and generic drugs, respectively; • a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; • extension of a manufacturer' s Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; • expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133 % of the federal poverty level, thereby potentially increasing a manufacturer' s Medicaid rebate liability; • a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70 % point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer' s outpatient drugs to be covered under Medicare Part D; • expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and • a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. There have been executive legal and political challenges to certain aspects of the ACA. For example, on June 17, 2021 the United States 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. Further, prior to the United States Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began February 15, 2021 and remained open through August 15, 2021. 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. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA. Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, 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

sequestration. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from 3 to 5 years. Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, which ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit- based Incentive Payment System, or MIPS. In November 2019, the Centers for Medicare & Medicaid Services, or CMS, issued a final rule finalizing the changes to the Quality Payment Program. At this time, it remains unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement. Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration' s proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the United States Department of Health and Human Services, or 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~~ **2023** to January 1, ~~2023~~ **2026** . The rule also creates a new safe harbor for price reductions reflected at the point- of- sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2023. On November 20, 2020, CMS issued an interim final rule 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. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinds the Most Favored Nation interim final rule. 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 to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform measures. 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. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. In particular, it is possible that additional governmental action is taken in response to the COVID- 19 pandemic. Any reduction in reimbursement from Medicare or other government- funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain sustained profitability or commercialize our drugs, particularly since the majority of our current revenue is derived from federal healthcare programs, including Medicare and Medicaid. We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry may be enacted in the future or what effect recently enacted federal legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to enter into collaboration agreements for the further development and commercialization of our product. Our clinical activities involve the handling of hazardous materials, and we must comply with environmental laws and regulations, which can be expensive and restrict how we do business. Our clinical activities involve the controlled storage, use and disposal of hazardous materials. We are subject to federal, state, city and local environmental, health and safety laws and regulations governing, among other matters, the use, manufacture, storage, handling and disposal of these hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or if we fail to comply with such laws and regulations, local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations or impose sanctions, such as fines, and we could be held liable for any resulting damages or liabilities. We do not currently maintain hazardous materials insurance coverage. Risks Related to Our Common Stock Our common stock may be delisted if we fail to comply with continued listing standards. If we fail to meet any of the continued listing standards of The Nasdaq Capital Market, our common stock could be delisted from The Nasdaq Capital Market. These continued listing standards include specifically enumerated criteria, such as: • a $ 1. 00 minimum closing bid price; • stockholders' equity of $ 2. 5 million; • 500, 000 shares of publicly- held common stock with a market value of at least $ 1 million; • 300 round- lot stockholders; and • compliance with Nasdaq' s corporate governance requirements, as well as additional or more stringent criteria that may be applied in the exercise of Nasdaq' s discretionary authority. ~~On June 3, 2022, we received written notice (the" Notice") from the Nasdaq Stock Market,~~

~~LLC (" Nasdaq") indicating that the bid price for our common stock, for the last 30 consecutive business days, had closed below the minimum $ 1. 00 per share and, as a result, we are not in compliance with the $ 1. 00 minimum bid price requirement for the continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550 (a) (2). In accordance with the Nasdaq Listing Rule 5810 (c) (3) (A), we had a period of 180 calendar days, or until November 30, 2022, to regain compliance with the minimum bid price requirement. On December 1, 2022, Nasdaq notified us that we were eligible for an additional 180 calendar days, or until May 30, 2023 to regain compliance. If we do not comply by May 30, 2023, Nasdaq will notify us that our common stock will be delisted and we will be able to appeal that determination.~~ If we fail to comply with Nasdaq' s continued listing standards, we may be delisted and our common stock will trade, if at all, only on the over- the- counter market, such as the OTC Bulletin Board, or OTCQX market, and then only if one or more registered broker- dealer market makers comply with quotation requirements. In addition, delisting of our common stock could depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Finally, delisting of our common stock could result in our common stock becoming a " penny stock " under the Exchange Act. If we fail to comply with the rules under the Sarbanes- Oxley Act of 2002 related to accounting controls and procedures in the future, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. If we fail to comply with the rules under the Sarbanes- Oxley Act of 2002 related to disclosure controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Section 404 of the Sarbanes- Oxley Act requires annual management assessment of the effectiveness of our internal control over financial reporting. As of December 31, ~~2022~~ **2023**, our management has determined that we had material weaknesses in our control environment and in the period end financial close and reporting process. If additional material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes- Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our Common Stock could drop significantly. The market price of our common stock may be volatile and adversely affected by several factors. The market price of our common stock could fluctuate significantly in response to various factors and events, including: • our ability to integrate operations, technology, products and services; • our ability to execute our business plan; • operating results below expectations; • our issuance of additional securities, including debt or equity or a combination thereof, which will be necessary to fund our operating expenses; • announcements of technological innovations or new products by us or our competitors; • loss of any strategic relationship; • industry developments, including, without limitation, changes in healthcare policies or practices or third- party reimbursement policies; • economic and other external factors; • period- to- period fluctuations in our financial results; • catastrophic weather and / or global disease outbreaks, such as the recent COVID- 19 pandemic; and • whether an active trading market in our common stock ~~develops and~~ is maintained. In addition, the securities markets have from time- to- time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock. The stock market in general has recently experienced relatively large price and volume fluctuations, particularly in response to the COVID- 19 outbreak. In particular, the market prices of securities of smaller biotechnology and medical device companies have experienced dramatic fluctuations that often have been unrelated or disproportionate to the operating results of these companies. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. In addition, price volatility may increase if the trading volume of our common stock remains limited or declines. U. S. federal income tax reform could adversely affect us. On December 22, 2017, the " Tax Cuts and Jobs Act " (TCJA) was signed into law that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to U. S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, and puts into effect the migration from a " worldwide " system of taxation to a territorial system. The tax reform has not caused a material impact to our projection of minimal cash taxes or to our net operating losses as of December 31, ~~2019~~ **2023**, the date of these consolidated financial statements ~~. Our net deferred tax assets and liabilities were adjusted, and the impact of $ 0. 5 million was recognized as an income tax benefit during the first quarter of 2018~~. The impact of this tax reform on holders of our common stock is uncertain and could be adverse. This Annual Report on Form 10- K does not discuss any such tax legislation or the manner in which it might affect purchasers of our common stock. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock. Certain provisions in our certificate of incorporation and by- laws, and of Delaware law, may prevent or delay an acquisition of our company, which could decrease the trading price of our common stock. Our certificate of incorporation, by- laws and Delaware law contain provisions that are intended to deter coercive takeover practices and inadequate takeover bids by making such practices or bids unacceptably expensive to the raider and to encourage prospective acquirers to negotiate with our board of directors rather than to attempt a hostile takeover. These provisions include, among others: • the inability of our stockholders to call a special meeting; • rules regarding how stockholders may present proposals or nominate directors for election at stockholder meetings; • the right of our board to issue preferred stock without stockholder approval; • the ability of our directors, and not stockholders, to fill vacancies on our board of directors. Delaware law also imposes some restrictions on mergers and other business combinations between us and any holder of 15 % or more of our outstanding common stock. ~~For more information, see " Description of Our Capital Stock — Anti- takeover Effects of Certain Provisions of Hepion Certificate of Incorporation, By- laws and the DCGL. "~~ We believe these

provisions will protect our stockholders from coercive or otherwise unfair takeover tactics by requiring potential acquirers to negotiate with our board of directors and by providing our board of directors with more time to assess any acquisition proposal. These provisions are not intended to make our company immune from takeovers. However, these provisions will apply even if the offer may be considered beneficial by some stockholders and could delay or prevent an acquisition that our board of directors determines is not in the best interests of our company and our stockholders. These provisions may also prevent or discourage attempts to remove and replace incumbent directors. Future sales and issuances of our common stock or rights to purchase common stock pursuant to our equity incentive plan could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall. We expect that significant additional capital will be needed in the future to continue our planned operations, including expanding research and development, funding clinical trials, purchasing of capital equipment, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. We may be at risk of securities class action litigation. We may be at risk of securities class action litigation. This risk is especially relevant for us due to our dependence on positive clinical trial outcomes and regulatory approvals of rencofilstat. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business and results in a decline in the market price of our common stock. If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. We presently do not intend to pay cash dividends on our common stock. We expect that no cash dividends will be paid on the common stock in the foreseeable future. While our dividend policy will be based on the operating results and capital needs of the business, it is anticipated that all earnings, if any, will be retained to finance the future expansion of our business.