Risk Factors Comparison 2025-03-19 to 2024-03-13 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all other information in this Annual Report on Form 10- K, including our consolidated financial statements and related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " before investing in our common stock. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations. The market price of our common stock could decline if one or more of these risks or uncertainties actually occur, causing you to lose all or part of the money you paid to buy our common stock. Certain statements below are forward- looking statements. See " Forward- Looking Statements " in this Annual Report on Form 10- K. Risks Related to our Products and Product Candidates Risks Related to Approval and Commercialization of our Products and Product Candidates We are heavily dependent on the success of our product candidates and our approved product, FUROSCIX. We cannot give any assurance that we will receive regulatory approval for any product candidates, which is necessary before they can be commercialized. To date, we have expended significant time, resources and effort on the development of our product candidates and our approved product, FUROSCIX, which we announced in October 2022 was approved by the U. S. Food and Drug Administration, or FDA. A substantial majority of our resources have also been focused on the commercial launch of FUROSCIX in the United States, which commenced in the first quarter of 2023. Our business and future success are substantially dependent on our ability to continue to successfully commercialize FUROSCIX for the treatment of congestion due to fluid overload in adults with ~~New York Heart Association Class II / III~~ chronic heart failure. All of our other product candidates are in early stages of development and subject to the risks of failure inherent in developing drug products. Accordingly, our ability to generate significant product revenues in the near term will depend almost entirely on our ability to successfully commercialize FUROSCIX. We are not permitted to market any of our product candidates in the United States until we receive approval of a new drug application, or NDA, from the U. S. Food and Drug Administration, or FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. There can be no assurance that the FDA will approve any of our product candidates, which is necessary before they can be commercialized. Satisfaction of regulatory requirements can be protracted, is dependent upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources. The time required to obtain approval by the FDA and comparable foreign regulatory 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. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. We cannot predict whether we will obtain regulatory approval to commercialize any of our product candidates, and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any. Any further delay or setback in the regulatory approval or commercialization of any of these product candidates will adversely affect our business. Even if we were to obtain approval of our product candidates, regulatory authorities may approve such product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, may impose distribution or use restrictions, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. We expect to rely on third-party consultants to assist us in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish a product candidate' s safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. If we cannot successfully obtain approval of our product candidates, our business will be materially harmed and the price of our common stock will be adversely affected. There is no assurance that our commercialization efforts with respect to FUROSCIX will be successful or that we will be able to generate revenues at the levels or within the timing we expect or at the levels or within the timing necessary to support our goals. FUROSCIX and the activities associated with its development and commercialization, including its design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and similar foreign regulatory authorities outside the United States. Failure to obtain marketing approval for FUROSCIX outside the United States will prevent us from commercializing it in those jurisdictions. Our ability to successfully commercialize FUROSCIX and any of our products candidates, if approved, will depend, among other things, on our ability to: • receive marketing approvals from the FDA and similar foreign regulatory authorities; • produce, through a validated process, sufficiently large quantities of FUROSCIX and our product candidates, if approved, to permit successful commercialization; • establish and maintain commercial manufacturing arrangements with third- party manufacturers; • build and maintain sales, distribution and marketing capabilities sufficient to launch and support commercial sales of FUROSCIX, as well as, our product candidates, if and when approved; • successfully complete our clinical trials for our product candidates under clinical development; • establish collaborations with third parties for the commercialization of our product candidates in countries outside the United States and such collaborators' ability to

obtain regulatory and reimbursement approvals in such countries; • secure acceptance of our product candidates from physicians, healthcare payers, patients and the medical community; and • manage our spending as costs and expenses increase due to clinical trials, regulatory approvals and commercialization. There are no guarantees that we will be successful in completing these tasks. If we are unable to successfully complete these tasks, we may not be able to successfully commercialize FUROSCIX or any of our product candidates, if approved, in a timely manner, or at all, in which case we may be unable to generate sufficient revenues to sustain and grow our business. Even though we obtained FDA approval for FUROSCIX in the United States, we may never obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize its full market potential. In order to market products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, the clinical standards of care may differ significantly such that clinical trials conducted in one country may not be accepted by healthcare providers, third- party payers or regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional drug testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any drug we develop will be unrealized. Risks Related to Clinical Development Clinical and preclinical development involves a lengthy and expensive process with an uncertain outcome. Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects. Before obtaining approval from regulatory authorities for the commercialization of any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate in humans. Preclinical and clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high. The results from preclinical studies or early clinical trials of a product candidate may not predict the results of later clinical trials of the product candidate, and interim results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. Before we can initiate clinical trials for any product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an Investigational New Drug Application, or IND, or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs. Moreover, even if we commence clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our ongoing and planned clinical trials for our product candidates could significantly affect our product development timelines and product development costs and harm our financial position. We do not know whether our planned clinical trials will begin on time or be completed on schedule, if at all. The commencement, data readouts and completion of clinical trials can be delayed for a number of reasons, including delays related to: • inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials; • obtaining allowance or approval from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design; • the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials; • any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • delays in identifying, recruiting and training suitable clinical investigators; • obtaining approval from one or more institutional review boards, or IRBs, or ethics committees at clinical trial sites; • IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial; • changes or amendments to the clinical trial protocol; • clinical sites deviating from the trial protocol or dropping out of a trial; • failure by our CROs to perform in accordance with Good Clinical Practice, or GCP, requirements or applicable regulatory rules and guidelines in other countries; • manufacturing sufficient quantities of our product candidates, or obtaining sufficient quantities of combination therapies for use in clinical trials; • subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post- treatment follow- up, including subjects failing to remain in our trials; • patients choosing an alternative product for the indications for which we are developing our product candidates, or participating in competing clinical trials; • lack of adequate funding to continue a clinical trial, or costs being greater than we anticipate; • subjects experiencing severe or serious unexpected drug- related adverse effects; • occurrence of serious adverse events in trials of the same class of

agents conducted by other companies that could be considered similar to our product candidates; • selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data; • transfer of manufacturing processes to larger- scale facilities operated by a contract manufacturing organization, or CMO, delays or failure by our CMOs or us to make any necessary changes to such manufacturing process, or failure of our CMOs to produce clinical trial materials in accordance with current Good Manufacturing Practice, or cGMP, regulations or other applicable requirements; and • third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner. Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations and guidelines, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or applicable clinical trial protocols, adverse findings from inspections of clinical trial sites by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators or to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates. In addition, many of the factors that cause, or lead to, the termination suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects. In addition, the FDA' s and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the **European Union, or** EU, recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi- center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state' s decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR ~~foresees a three- year~~ transition period **ended on** ~~. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to~~ January 31, ~~2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31,~~ 2025 ~~. After this date~~ , **and** all clinical trials (~~including those which~~ **and related applications)** are **now fully** ~~ongoing) will become~~ subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third- party service providers, such as CROs, may impact our developments plans. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow- up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial' s conclusion as required by the FDA or other comparable regulatory authorities. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. Patient enrollment for any of our clinical trials may be affected by other factors, including: • size and nature of the targeted patient population; • severity of the disease or condition under investigation; • availability and efficacy of approved therapies for the disease or condition under investigation; • patient eligibility criteria for the trial in question as defined in the protocol; • perceived risks and benefits of the product candidate under study; • clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any products that may be approved for, or any product candidates under investigation for, the indications we are investigating; • efforts to facilitate timely enrollment in clinical trials; • patient

referral practices of physicians; • the ability to monitor patients adequately during and after treatment; • proximity and availability of clinical trial sites for prospective patients; • continued enrollment of prospective patients by clinical trial sites; • the risk that patients enrolled in clinical trials will drop out of such trials before completion; and • delays or difficulties in enrollment and completion of studies due to health emergencies or global events. Additionally, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. We also rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we will have limited influence over their actual performance. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain regulatory approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials. Our products and product candidates may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during the development of our product candidates or following approval, if any, we may need to abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any. Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. For example, the most common adverse events observed in clinical trials of FUROSCIX included the following administration site and skin reactions: erythema, bruising, edema and infusion site pain, which are listed on the approved label for FUROSCIX. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. It is possible that there may be side effects associated with our other product candidates' use. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such products (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw or limit their approval of such products; • regulatory authorities may require the addition of labeling statements, such as a REMS, " boxed " warning or a contraindication; • we may be required to change the way such products are distributed or administered, conduct additional clinical trials or change the labeling of the products; • we may be subject to regulatory investigations and government enforcement actions; • we may decide to recall or remove such products from the marketplace; or • we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; or • we may fail to secure acceptance of our product candidates from physicians, healthcare payers, patients and the medical community; and • our reputation may suffer. We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected products, and could substantially increase the costs of commercializing our products and significantly impact our ability to successfully commercialize our products and generate revenues. Any of these occurrences may harm our business, financial condition and prospects. Interim, " topline " and preliminary data from our clinical trials and preclinical studies that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose interim, topline, or preliminary data from our clinical trials and preclinical studies, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available. Interim data from clinical trials that we may complete are further subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, topline, or preliminary data and final data could significantly harm our business prospects. Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize,

our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. Our failure to successfully identify, develop and market additional product candidates could impair our ability to grow. As part of our growth strategy, we intend to identify, develop and market additional products beyond FUROSCIX. We may spend several years completing our development of any particular current or future internal product candidates, 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 companies, academic scientists and other researchers to sell or license product candidates, approved products or the underlying technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising product candidates and products. 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: • exposure to unknown liabilities; • 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; and • inability to motivate key employees of any acquired businesses. 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 other foreign regulatory authorities. Risks Related to Acceptance, Sales, Marketing and Competition The commercial success of FUROSCIX and any product candidates, if approved, depends upon attaining market acceptance by hospital networks, physicians, patients, third- party payers and the medical community. Even if our current and future product candidates are approved for commercialization by the appropriate regulatory authorities, physicians may not prescribe our approved product candidates, in which case we would not generate the revenues we anticipate. Market acceptance of FUROSCIX or any of our product candidates by physicians, patients, third- party payers and the medical community depends on, among other things: • our ability to provide acceptable evidence of safety and efficacy, at least equivalent to IV- level treatments; • perceived advantages of FUROSCIX or our product candidates over alternative treatments, such as oral and IV formulations; • relative convenience as well as ease of administration of FUROSCIX or our product candidates compared to existing treatments; • any labeling restrictions placed upon FUROSCIX or any product candidate in connection with its approval; • the prevalence and severity of the adverse side effects of FUROSCIX or our product candidates; • the clinical indications for which FUROSCIX or any of our product candidates is approved, including any potential additional restrictions placed upon each product candidate in connection with its approval; • prevalence of the disease or condition for which FUROSCIX or any product candidate is approved; • the cost of treatment in relation to alternative treatments, including generic products; • the extent to which each product is approved for use at, or included on formularies of, hospitals and managed care organizations; • any negative publicity related to our or our competitors' products or other formulations of products that we administer subcutaneously, including as a result of any related adverse side effects; • the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies; • pricing and cost effectiveness; and • the availability of coverage and adequate reimbursement by third parties. Successful commercialization will also depend on whether we can adequately protect against and effectively respond to any claims by holders of patents and other intellectual property rights that our products infringe upon their rights, whether any unanticipated adverse effects or unfavorable publicity develops in respect of our products, as well as the emergence of new or existing products as competition, which may be proven to be more clinically effective and cost- effective. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our approved product, FUROSCIX, we may be unable to generate adequate revenue. We are in the process of continuing to establish sufficient infrastructure for the sales, marketing or distribution of FUROSCIX and for our product candidates, and the cost of establishing and maintaining such an organization may exceed the benefits of doing so. In order to market FUROSCIX, we must continue to build our sales, marketing, managerial, and other non- technical capabilities or make arrangements with third parties to perform these services. We have established an initial in- house sales force to promote FUROSCIX to hospital networks, healthcare providers and third- party payers in the United States. There are significant expenses and risks involved with establishing our own sales and marketing capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. We cannot be sure that we will be able to hire **and retain** a sufficient number of sales representatives or that they will be effective at promoting FUROSCIX. In addition, we will need to commit significant additional management and other resources to establish and grow our sales organization. We may not be able to achieve the necessary development and growth in a cost- effective manner or realize a positive return on our investment. We will also have to compete with other companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize FUROSCIX and our product candidates, if approved, on our own include: • our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, our

business, results of operations, financial condition and prospects will be materially adversely impacted. Beyond FUROSCIX, we intend to leverage the sales and marketing capabilities that we establish for FUROSCIX to commercialize additional product candidates, if approved by the FDA, in the United States. If we are unable to do so for any reason, we would need to expend additional resources to establish commercialization capabilities for those product candidates, if approved. In addition, we intend to establish collaborations to commercialize our product candidates, if approved by the relevant regulatory authorities, outside of the United States. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such efforts, the collaborator' s strategic interest in the product and such collaborator' s ability to successfully market and sell the product. We cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do, or limit the market potential of FUROSCIX and our product candidates, if approved. We face and will continue to face competition from other companies in the pharmaceutical and medical device industries. We believe our technology and approach of developing proprietary formulations of medicines to be delivered subcutaneously will compete with the efforts of other companies seeking to develop similar therapies. These and other pharmaceutical companies are applying significant resources and expertise to the challenges of drug delivery. Some of these current and potential future competitors may be addressing the same therapeutic areas or indications as we are. Many of our current and potential future competitors have significantly greater research and development capabilities than we do, have substantially more marketing, manufacturing, financial, technical, human and managerial resources than we do, and have more institutional experience than we do. As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that allow them to develop and commercialize their products before us and limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs or devices that are more effective, more widely used and less costly than ours, and they may also be more successful than us in manufacturing and marketing their products **. In October 2024, the FDA awarded 3- year exclusivity to FUROSCIX, and, as a result, the FDA may not approve a subsequent product for subcutaneous administration of furosemide for 3 years from the date of approval of FUROSCIX, or October 7, 2025. Exclusivity may be revoked if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition** . If the FDA approves a competitor' s application for a product candidate or drug- device combination product before our application for a similar product candidate or drug- device combination product, and grants such competitor a period of exclusivity, the FDA may take the position that it cannot approve our 505 (b) (2) application for a similar product candidate until the exclusivity period expires. Additionally, even if our 505 (b) (2) application for any of our product candidates is approved first, we may still be subject to competition from other producers of heart failure and infectious disease therapies with approved products or approved 505 (b) (2) NDAs for different conditions of use that would not be restricted by any grant of exclusivity to us. The widespread acceptance of currently available therapies with which FUROSCIX and our product candidates will compete may limit market acceptance of FUROSCIX and our product candidates even if commercialized. Oral medication and IV drug delivery are currently available treatments for heart failure and are widely accepted in the medical community and have a long history of use. For example, the use of IV furosemide to treat decompensation in heart failure patients is well- established and has received widespread market acceptance. These treatments will compete with FUROSCIX and the established use of IV furosemide may limit the potential for FUROSCIX to receive widespread acceptance. Risks Related to Manufacturing, Supply and Use If we fail to produce FUROSCIX in the volumes that we require on a timely basis, we may face delays in our commercialization efforts. We do not currently own or operate manufacturing facilities for the production of FUROSCIX or any of our product candidates. We currently depend on third parties to manufacture our product candidates, including the drug formulation and device components for FUROSCIX, and continue to rely on such third parties to produce the final commercial product. Any future curtailment in the availability of materials 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. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Pharmaceutical companies often encounter difficulties in production, particularly in scaling up production, of their products. These problems include manufacturing difficulties relating to 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. Any delays in the manufacturing of finished drug product or device components could delay our commercial supply, which could delay, prevent or limit our ability to generate revenue and continue our business. Moreover, if we are unable to demonstrate stability in accordance with commercial requirements, or if our manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to obtain or maintain FDA or foreign regulatory authorities approval and market our product candidates would be jeopardized. In addition, any delay or interruption in the supply of clinical trial supplies could delay or prohibit the completion of our bioequivalence and / or clinical trials, increase the costs associated with conducting our bioequivalence and / or clinical trials and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate a trial. **Certain of our pharmaceutical products are manufactured outside of the United States. In certain years, the U. S. government has initiated substantial changes in U. S. trade policy and U. S. trade agreements, including the initiation of tariffs on certain foreign goods. In response to these tariffs, certain foreign governments, including Canada, China and Mexico, have instituted or are considering imposing tariffs on certain U. S. goods. If the U. S.**

imposes additional tariffs on a broader range of imports from certain countries, and in response those countries take further retaliatory trade measures, these actions could impose additional costs on our business. Increased tariffs could require us to increase our prices which could decrease demand for our product, and in certain cases we may be unable to pass along increased costs to our customers. Manufacturers of drug- device combination products, such as FUROSCIX, need to comply with both pharmaceutical current good manufacturing practice requirements, or cGMPs, and the FDA' s cGMP requirements for medical devices, known as the Quality System Regulation, or QSR, which is enforced by the FDA through its facilities inspection programs. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of FUROSCIX and our product candidates may be unable to comply with these cGMP and QSR requirements and with other FDA and foreign regulatory requirements. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. 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 of FUROSCIX or any of our product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize FUROSCIX or such product candidate, and we may be held liable for any injuries sustained as a result. Any of these factors could impact the commercialization of FUROSCIX or cause a delay in the commercialization of our other product candidates, entail higher costs or even prevent us from effectively commercializing FUROSCIX or our product candidates. Even if we successfully produce and distribute FUROSCIX, its success will be dependent on the proper use of FUROSCIX by patients, healthcare professionals and caregivers. While we believe FUROSCIX can be self- administered by patients, caregivers and healthcare practitioners in a clinic and home environment, we cannot control the successful use of the product by patients, caregivers and healthcare professionals. We make use of packaging and instructions for use to provide guidance to users of FUROSCIX, but we cannot ensure that the product will be used properly. If we are not successful in promoting the proper use of FUROSCIX by patients, healthcare professionals and caregivers, we may not be able to achieve market acceptance or effectively commercialize FUROSCIX. Additionally, any potential negative impact on patients stemming from the improper use of FUROSCIX may lead to reputational harm, result in negative press coverage, or increase the risk that we may be sued. Even in the event of proper use of FUROSCIX by patients, healthcare professionals and caregivers, individual devices may fail. We have increased manufacturing capabilities for production of FUROSCIX, but increasing scale of production inherently creates increased risk of manufacturing errors. We may not be able to adequately inspect every device that is produced, and it is possible that individual devices may fail to perform as designed. Manufacturing errors could negatively impact market acceptance of FUROSCIX, result in negative press coverage, or increase the risk that we may be sued. Risks Related to Our Financial Position and Capital Requirements Risks Related to Past Financial Condition We have a history of significant operating losses and expect to incur significant and increasing losses for the foreseeable future; we may never achieve or maintain profitability. We do not expect to generate revenue or profitability that is necessary to finance our operations in the short term. We incurred net losses of $ ~~36~~ **54** . 8 million and $ ~~54~~ **85** . ~~8~~ **1** million for the years ended December 31, ~~2022 and~~ 2023 **and 2024** , respectively. In addition, our accumulated deficit as of December 31, ~~2023~~ **2024** was $ ~~281~~ **366** . ~~3~~ **5** million. Absent the realization of sufficient revenues from product sales of FUROSCIX or our current or future product candidates, if approved, we may never attain profitability in the future. We have devoted substantially all of our financial resources and efforts to date to research and development, including preclinical studies and our clinical trials, and preparation for commercialization of FUROSCIX. We anticipate that our expenses will increase substantially if and as we: • continue to build our sales, marketing, distribution and other commercial infrastructure and manufacture commercial inventory of FUROSCIX; • initiate and continue research, preclinical and clinical development efforts for any current or future product candidates; • seek to identify additional product candidates; • seek regulatory and marketing approvals for product candidates that successfully complete clinical trials; • manufacture larger quantities of product candidates for clinical development and ~~,~~ ~~potentially,~~ commercialization; • maintain, expand and protect our intellectual property portfolio; • hire and retain additional personnel, such as clinical, quality control, commercial, scientific and sales and marketing personnel; • add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company; and • add equipment and physical infrastructure to support our research and development. Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue until we are able to successfully commercialize FUROSCIX or any other product candidates that we may develop. Successful commercialization will require achievement of key milestones, including completing clinical trials of our product candidates that are under clinical development, obtaining marketing approval for our product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing approval, satisfying any post- marketing requirements and obtaining reimbursement for our products from private insurance or government payers. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment. We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability. We commenced operations in 2013. Our operations up until

very recently have primarily been limited to financing and staffing our company, developing our technology and conducting preclinical research and clinical trials for our product candidates. We have only one product approved for commercial sale, and have limited experience in obtaining marketing approvals, manufacturing products on a commercial scale or arranging for a third party to do so on our behalf, and conducting sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully commercializing products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives **as we** ~~. We will need to~~ transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. In addition, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We may not generate substantial revenue from FUROSCIX and may never be profitable. Our ability to become profitable depends upon our ability to generate revenue. Our commercial launch of FUROSCIX commenced in the first quarter of 2023, and there is no assurance that we will **ever** generate substantial revenues from FUROSCIX. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to: • continue to obtain commercial quantities of FUROSCIX at acceptable cost levels; • obtain third- party coverage or adequate reimbursement for FUROSCIX; • achieve market acceptance of FUROSCIX in the medical community, with patients and with third- party payers, including placement in accepted clinical guidelines for the conditions for which FUROSCIX is intended to target; and • delay the introduction by competitors of alternate versions of FUROSCIX. We have incurred and expect to continue to incur significant sales and marketing costs as we commercialize FUROSCIX. Even if we expend these costs, FUROSCIX may not be a commercially successful product. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate substantial product revenue, we will not become profitable and may be unable to continue operations without continued funding. Risks Related to Future Financial Condition We may need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts. Developing our product programs is a time- consuming, expensive and uncertain process that takes years to complete. In addition, we may incur significant commercialization expenses for FUROSCIX or any of our product candidates, if approved, related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs or any commercialization efforts. We plan to continue to use our existing unrestricted cash primarily for development activities related to the advancement and commercialization of FUROSCIX, automation necessary to increase capacity for our delivery technology, research and development, and for working capital and other general corporate purposes. We will be required to expend significant funds in order to commercialize FUROSCIX, as well as other product candidates we may seek to develop. In any event, our existing unrestricted cash may not be sufficient to fund all of the efforts that we plan to undertake, including the development of any of our product candidates. Accordingly, we may be required to obtain further funding through public or private equity offerings, debt financings, royalty-based financing arrangements, collaborations and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. In addition, we maintain our cash and cash equivalents at a number of financial institutions, and our deposits at one or more of these institutions may exceed federally insured limits. Market conditions can impact the viability of one or more of these institutions and, in the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we will be able to access uninsured funds in a timely manner or at all. Our future funding requirements, both short- term and long- term, will depend on many factors, including: • the outcome, timing and costs of completing development and seeking regulatory approvals for product candidates that we may develop; • the costs of commercialization activities for FUROSCIX and any of our product candidates that receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities; • revenue, if any, received from commercial sales of FUROSCIX or any of our current and future product candidates; • the pricing and reimbursement of FUROSCIX and of any of our product candidates that may be approved; • the number of future product candidates that we pursue and their development requirements; • the scope, progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, our other product candidates; • our ability to enter into, and the terms and timing of, any collaborations, licensing or other arrangements; • our headcount growth and associated costs as we establish a commercial infrastructure and continue our research and development activities; • the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights including enforcing and defending intellectual property related claims; • costs associated with any adverse market conditions or other macroeconomic factors; and • the costs of operating as a public company. The terms of our credit facility **and revenue participation financing facility** place restrictions on our operating and financial flexibility, and we may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due. In ~~October~~ **August** ~~2022~~ **2024**, we entered into a Credit Agreement and Guaranty (the ~~“~~ **"** Credit Agreement ~~”~~ **"**), ~~with Oaktree Fund Administration~~ **by and among us**, ~~LLC~~ **the guarantors from time to time party thereto**, **the lenders from time to time party thereto (the" Lenders"), and Perceptive Credit Holdings IV, LP, in its capacity** as **administrative** agent **for the Lenders** ~~and certain funds managed by Oaktree Capital Management, L. P.~~ (~~“ Oaktree ”~~ **in such capacity, the" Agent"**) ~~, as lenders~~. The Credit Agreement establishes a $ ~~100~~ **75**. 0 million term loan facility, consisting of (i) ~~a~~ $ 50. 0 million ~~tranche the~~ (**the** “ Tranche A Loan ”) ~~, which was~~ funded ~~at~~ **on the** closing **date**, (ii) ~~a~~ $ 25. 0 million ~~tranche~~ (the “ Tranche B Loan ” **and, together with the Tranche A Loan, collectively, the “ Term Loan ”**) ~~, which~~ **that the** we may borrow in **a single borrowing** ~~up to two draws~~ on or prior to **March** ~~September 30, 2024, and (iii) $ 25. 0 million, or the Tranche C Loan, that we may borrow~~

~~on or prior to December~~ 31, ~~2024~~ **2026** ; provided ~~that~~ , in the case of the Tranche B Loan ~~and the Tranche C Loan~~ , that we **and our subsidiaries** have **obtained certain regulatory approval and** achieved certain net sales ~~revenue milestone~~ targets **, each as** described in the Credit Agreement. ~~All~~ **Our** obligations under the Credit Agreement **and the other Loan Documents (as defined in the Credit Agreement) will be guaranteed by any domestic subsidiaries of ours that become Guarantors (as defined in the Credit Agreement), subject to certain exceptions. Our obligations under the Credit Agreement and the other Loan Documents** are secured by **first priority security interests in** substantially all of our ~~existing property and~~ assets ~~(including our intellectual property assets)~~ , subject to certain **customary thresholds and** exceptions. **As** ~~This debt financing may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off~~ - **of** ~~or refinancing our outstanding debt obligations at maturity~~ **the closing date, there were no Guarantors** . The Credit Agreement contains customary representations, warranties and affirmative and negative covenants, including financial covenants requiring us to (i) maintain certain levels of cash and cash equivalents in accounts subject to a control agreement in favor of ~~Oaktree~~ **the Agent** of at least $ ~~15~~ **5** . 0 million **at all times** ~~and increasing to $ 20. 0 million of cash and cash equivalents in such controlled accounts~~ after ~~we borrow~~ the **closing date** ~~Tranche B Loan,~~ and (ii) meet minimum quarterly net sales ~~revenue~~ targets described in the Credit Agreement. In addition, the Credit Agreement contains customary events of default that entitle ~~Oaktree~~ **the Agent** to ~~accelerate~~ **cause** our indebtedness under the Credit Agreement to become immediately due and payable **, and to exercise remedies against us and the collateral securing the Term Loan, including cash** . Under the Credit Agreement, an event of default will occur if, among other things, we fail to make payments under the Credit Agreement (subject to specified ~~cure~~ periods ~~for nonpayment of interest or other non- principal obligations~~) ~~;~~ **,** we or our subsidiaries breach any of the covenants under the Credit Agreement (subject to specified cure periods with respect to certain breaches) ~~;~~ **, a material adverse change occurs,** we, our subsidiaries or ~~our~~ **their** respective assets become subject to certain legal proceedings, such as bankruptcy proceedings ~~;~~ **,** we and / or our subsidiaries are unable to pay our debts as they become due ~~; we and / or our~~ - **or** ~~subsidiaries~~ default on ~~any contract~~ **contracts** ~~for material~~ **with third parties which would permit the holder of** indebtedness ~~that would allow~~ **in excess of a certain threshold to accelerate** the ~~holder~~ **maturity** of such indebtedness **or that could cause a material adverse change. Upon the occurrence and for the duration of an event of default, an additional default interest rate equal** to ~~accelerate~~ **3. 0 % per annum may apply to all obligations owed under the Credit Agreement. We intend to satisfy our current and future debt service obligations with our** ~~the~~ **then** ~~maturity of such indebtedness~~ **existing cash and cash equivalents. However, we may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under the Credit Agreement or any other debt instruments** . Failure to satisfy our current and future debt obligations, including covenants to take or avoid specific actions, under the Credit Agreement could result in an event of default and, as a result, ~~our~~ **the** ~~lenders~~ **Lenders** could accelerate all of the amounts due. In the event of an acceleration of amounts due under the Credit Agreement as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness while still pursuing our current business strategy. In addition, ~~our~~ **the** ~~lenders~~ **Lenders** could seek to enforce their security interests in any collateral securing such indebtedness **. In August 2024, we also entered into a revenue participation right purchase and sale agreement (the" Revenue Purchase and Sale Agreement") with Perceptive Credit Holdings IV, LP (the" Purchaser"). Under the terms of the Revenue Purchase and Sale Agreement, in exchange for the Purchaser' s payment to us of a purchase price of $ 50. 0 million, in the aggregate subject to certain conditions at closing (the " Purchase Price "), we have agreed to sell to the Purchaser its right to receive payment in full of a tiered single digit percentage of net sales of FUROSCIX (the " Revenue Payment ") for each calendar quarter commencing on the effective date of the Revenue Purchase and Sale Agreement, subject to adjustments on June 30, 2028 and June 30, 2030 depending on the amount of Revenue Payments received by such dates. The Purchaser' s right to receive the Revenue Payment terminates and we no longer have the obligation to pay Purchaser Revenue Payments once the Purchaser receives 200. 0 % (subject to reductions on September 30, 2027 and September 30, 2029 depending on the amount of Revenue Payments received by such dates) of the Purchase Price. We may also buy- out the Purchaser' s rights to receive the Revenue Payments by paying Purchaser a tiered multiple on the Purchaser Price. The Revenue Purchase and Sale Agreement contains various representations and warranties, including with respect to organization, authorization, and certain other matters, certain covenants with respect to payment, reporting, intellectual property, in- licenses, out- licenses, and certain other actions, indemnification obligations and other provisions customary for transactions of this nature. Payment requirements under the Revenue Purchase and Sale Agreement will increase our cash outflows. Our future operating performance is subject to market conditions and business factors that are beyond our control. If our cash inflows and capital resources are insufficient to allow us to make required payments, we may have to reduce or delay capital expenditures, sell assets or seek additional capital. If we raise funds by selling additional equity, such sale would result in dilution to our shareholders. There is no assurance that if we are required to secure funding we can do so on terms acceptable to us, or at all. Failure to pay amounts owed to the Purchasers when due would result in a default under the Revenue Purchase and Sale Agreement and could result in foreclosure on all or substantially all of our assets, which would have a material adverse effect** . Risks Related to Government Regulation Risks Related to Ongoing Regulatory Obligations The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. The clinical development, manufacturing, labeling, storage, record- keeping, advertising, promotion, import, export, marketing and distribution of our products and product candidates are subject to extensive regulation by the FDA in the U. S. and by comparable foreign regulatory authorities in foreign markets. In the U. S., we are not permitted to market our product candidates in the U. S. until we receive regulatory approval of a NDA from the FDA. The process of obtaining such regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the

type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA and comparable regulatory have substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval of a product candidate is never guaranteed. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. Prior to obtaining approval to commercialize a product candidate in the U. S. or abroad, we must demonstrate with substantial evidence from adequate and well- controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe available nonclinical or clinical data support the safety or efficacy of our product candidates, such data may not be sufficient to obtain approval from the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post- approval, or may object to elements of our clinical development program. The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including: • such authorities may disagree with the design or execution of our clinical trials; • negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval; • serious and unexpected drug- related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates; • the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval; • such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country; • we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; • such authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a NDA or other submission or to obtain regulatory approval in the U. S. or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials; • such authorities may disagree with us regarding the formulation, labeling and / or the product specifications of our product candidates; • approval may be granted only for indications that are significantly more limited than those sought by us, and / or may include significant restrictions on distribution and use; • such authorities may find deficiencies in the manufacturing processes or facilities of the third- party manufacturers with which we contract for clinical and commercial supplies; or • such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission. With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. Additionally, the FDA regulates FUROSCIX as a combination product that consists of both a drug and a medical device, and we may develop product candidates or additional presentations of FUROSCIX that are similarly regulated as combination products ~~. For example, we are developing an 80mg / 1mL auto- injector designed to provide an additional option to the on- body infusor for FUROSCIX for eligible adult patients who do not require hospitalization~~ . Developing and obtaining regulatory approval for combination products can pose unique challenges because they involve components that are regulated under different types of regulatory requirements and potentially by different FDA centers. As a result, such product candidates may raise regulatory, policy and review management challenges. Differences in regulatory pathways for each component of a combination product can impact the regulatory processes for all aspects of product development and management, including clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, user fees and post approval modifications. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. **For example, we are developing an 80mg / 1mL auto-injector designed to provide an additional option to the on- body infusor for FUROSCIX for eligible adult patients who do not require hospitalization. We submitted an IND in February 2024, initiated a pharmacokinetic / pharmacodynamic (PK / PD) study in April of 2024, and completed enrollment in May 2024 with positive data announced in August 2024. In December 2024, we disclosed that we had observed variability during shelf- life testing in one lot of the combination product.** Even if we eventually complete clinical trials and receive approval of a NDA or comparable foreign marketing application for any of our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and / or the implementation of a REMS, which may be required because the FDA believes it is necessary to ensure safe use of the product after approval. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects. Even though the FDA has approved FUROSCIX, we will remain subject to significant post- marketing regulatory requirements and oversight. In October 2022, the FDA approved FUROSCIX for the treatment of congestion due to fluid overload in adults with NYHA Class II / III chronic heart failure. **Subsequently, in August 2024, the FDA approved the expansion of the FUROSCIX indication to include NYHA Class IV heart failure patients.** In connection with ~~this~~ **these** ~~approval~~ **approvals** , or any other approvals we may obtain for FUROSCIX or any of our product candidates, we are required to submit reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product. In addition, approved labeling for our products may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post- approval study or risk management requirements. For example, the approved labeling for FUROSCIX includes contraindications for patients with anuria, hypersensitivity to furosemide and hepatic cirrhosis or ascites, and is not approved for use in emergency situations or in

patients with acute pulmonary edema ~~. The FDA may also require a REMS in order to approve a product candidate, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools~~ . In addition, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products are subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as on- going compliance with current good manufacturing practices, or cGMPs, and GCPs for any clinical trials that we conduct post- approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP and comparable foreign regulations and standards. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including: • delays in or the rejection of product approvals; • restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials; • restrictions on the products, manufacturers or manufacturing process; • warning or untitled letters; • civil and criminal penalties; • injunctions; • suspension or withdrawal of regulatory approvals; • product seizures, detentions or import bans; • voluntary or mandatory product recalls and publicity requirements; • total or partial suspension of production; and • imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize FUROSCIX and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. In addition, the FDA' s and other regulatory authorities' policies may change, and additional government regulations may be enacted that could impair our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, and we may not achieve or sustain profitability. If we are unable to achieve and maintain coverage and adequate levels of reimbursement for FUROSCIX and any of our product candidates, if approved, their commercial success may be severely hindered. Successful sales of FUROSCIX and any product candidates that receive regulatory approval depend on the availability of adequate coverage and reimbursement rates from third- party payers, including governmental healthcare programs, such as Medicare and Medicaid, commercial payers, and health maintenance organizations. Patients who are prescribed medications for the treatment of their conditions generally rely on third- party payers to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement rates from governmental healthcare programs and commercial payers is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even if we obtain coverage for a given product, the resulting reimbursement rates might not be sufficient to achieve or sustain profitability or may require co- payments that patients find unacceptably high, thereby discouraging their use of our products. Additionally, third- party payers may not cover, or provide adequate reimbursement for, long- term follow- up evaluations required following the use of our product candidates. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. In addition, the market for FUROSCIX and any product candidates that we attempt to commercialize will depend significantly on access to third- party payers' drug formularies, or lists of medications for which third- party payers provide coverage. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third- party payers may refuse to include a particular branded drug in their formularies, or may apply formulary controls (e. g., prior authorization or step therapy requirements, higher co- payments) to restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. Third- party payers, whether foreign or domestic, and whether governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In the United States, no uniform policy for coverage and reimbursement of products exists among third- party payers. The Centers for Medicare & Medicaid Services, or CMS, an agency within the U. S. Department of Health and Human Services, or HHS, decides whether and to what extent products will be covered and reimbursed under Medicare. Third- party payers often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. Reimbursement by a third- party payer may depend upon a number of factors, including the third- party payer' s determination that a medication is safe, effective and medically necessary; appropriate for the specific patient; cost- effective; supported by peer- reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental nor investigational. Therefore, coverage of and reimbursement rates for products can differ significantly from payer to payer. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific, clinical, and cost- effectiveness data for the use of our products to each payer separately, with no assurance that coverage will be applied consistently or obtained in the first instance. There may also be delays in obtaining coverage for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, for example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services. We may also increasingly be required to provide discounts on our products to governmental healthcare programs, commercial payers and health maintenance organizations. Further, we believe that future coverage and reimbursement rates will likely be subject to increased restrictions both in the United States and in

international markets. Third- party coverage for our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects. If the FDA does not conclude that our product candidates satisfy the requirements for the Section 505 (b) (2) regulatory approval pathway, or if the requirements for such product candidates under Section 505 (b) (2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful. In October 2022, the FDA approved our NDA for FUROSCIX through the Section 505 (b) (2) regulatory pathway, and we plan to develop additional product candidates for which we plan to seek approval under the 505 (b) (2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505 (b) (2) to the FDCA. Section 505 (b) (2) permits the submissions of a NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505 (b) (2), if applicable to us under the FDCA, would allow a NDA we submit to the FDA to rely in part on data in the public domain or the FDA' s prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our future product candidates by potentially decreasing the amount of nonclinical and / or clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505 (b) (2) regulatory pathway for our product candidates, we may need to conduct additional nonclinical studies and / or clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for such product candidates, and complications and risks associated with such product candidates, would likely substantially increase. Moreover, inability to pursue the Section 505 (b) (2) regulatory pathway could result in new competitive products reaching the market more quickly than any product candidates we developed, which could adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505 (b) (2) regulatory pathway, we cannot assure you that any product candidates we develop will receive the requisite approval for commercialization. In addition, ~~notwithstanding the approval of a number of products by the FDA under Section 505 (b) (2), certain pharmaceutical companies and others have objected to the FDA' s interpretation of Section 505 (b) (2). If the FDA' s interpretation of Section 505 (b) (2) is successfully challenged, the FDA may change its 505 (b) (2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505 (b) (2). In addition,~~ the pharmaceutical industry is highly competitive, and Section 505 (b) (2) NDAs are subject to certain requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505 (b) (2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of a new product. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505 (b) (2) regulatory pathway, there is no guarantee this would ultimately lead to streamlined product development or earlier approval. If the FDA or other foreign regulatory authorities approve generic products that compete with FUROSCIX or any of our product candidates, the sales of FUROSCIX or our product candidates, if approved, could be adversely affected. Once a NDA, including a Section 505 (b) (2) application, is approved, the product covered becomes a " listed drug " which can be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. FDA regulations and other foreign regulations and policies provide incentives to manufacturers to create modified versions of a drug to facilitate the approval of an ANDA or other application for similar substitutes. If these manufacturers demonstrate that their product has the same active ingredient (s), dosage form, strength, route of administration, and conditions of use, or labeling, as FUROSCIX or any of our product candidates, they might only be required to conduct a relatively inexpensive study to show that their generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, FUROSCIX or our product candidate (and in some cases even this limited bioequivalence testing can be waived by the FDA). Competition from generic equivalents to FUROSCIX or any of our product candidates could substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in FUROSCIX and our product candidates. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions. We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval

may adversely impact our business. Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a trademark registration from the U. S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may object to any product name we submit if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate, and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates. Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs. The Foreign Corrupt Practices Act, or FCPA, prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non- United States government official in order to influence official action, or otherwise obtain or retain business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Our business is heavily regulated and therefore involves significant interaction with public officials, which may in the future include officials of non- United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers would be subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or SEC, and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non- U. S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with anti- bribery and anti- corruption laws, and other laws governing international business practices, may result in substantial fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of heightened monitoring by governmental authorities, and prohibitions on the conduct of our business. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any. In some countries, such as the countries of the **EU** ~~European Union~~ , the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low- priced and high- priced countries, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we, or any future collaborators, may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidates to other available therapies, which is time- consuming and costly. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed. We may be liable if the FDA or other U. S. enforcement agencies determine we have engaged in the off- label promotion of our products or have disseminated false or misleading labeling, advertising or promotional materials. The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct- to- consumer advertising, industry- sponsored scientific and educational activities, promotional activities involving the internet and off- label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. For example, the FDA- approved label for FUROSCIX is limited to the treatment of congestion due to fluid overload in adults with ~~NYHA Class II / III~~ chronic heart failure, and includes **certain contraindications and** limitations ~~prohibiting~~ **on** use ~~in emergency situations or patients with pulmonary edema~~ . Our promotional materials and training methods must comply with the FDA and other applicable laws and regulations, including laws and regulations prohibiting marketing claims that promote the off- label use of our products or that omit material facts or make false or misleading statements about the safety or efficacy of our products. Healthcare providers may use our products, if approved, off- label, as the FDA does not restrict or regulate a physician' s choice of treatment within the practice of medicine. The FDA also could conclude that a claim is misleading if it determines that there are inadequate nonclinical and / or clinical data supporting the claim, or if a claim fails to reveal material facts about the safety or efficacy of our products. If the FDA determines that our promotional labeling or advertising materials promote an off- label use or make false or misleading claims, it could request that we modify our promotional materials or training content or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fines and criminal penalties. It is also

possible that other federal, state or foreign enforcement authorities might take action if they determine that our promotional or training materials promote an unapproved use or make false or misleading claims, which could result in significant fines or penalties. The FDA or another regulatory agency could disagree with the manner in which we advertise and promote our products. Violations of the FDCA may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws, which may lead to costly penalties and may adversely impact our business. Recent court decisions have impacted FDA' s enforcement activity regarding off- label promotion in light of First Amendment considerations; however, there are still significant risks in this area, in part due to the potential for False Claims Act exposure. In addition, the off- label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation. Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of any product candidates and commercialize FUROSCIX and may affect the prices we may obtain. In the United States and many foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of any of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell FUROSCIX or any product candidates for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record- keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the ACA, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our products and product candidates are the following: • an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs; • a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; • 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; • expansion of potential liability under federal healthcare fraud and abuse laws, including the False Claims Act, or FCA, and the Anti- Kickback Statute, or AKS; • a new Medicare Part D coverage gap discount program, **which was replaced by a new manufacturer discount program on January 1, 2025 (as discussed below),** in which manufacturers ~~must agree~~ **were required** to offer 50 % (70 % as of January 1, 2019 due to the Bipartisan Budget Act of 2018, or the BBA) point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D; • extension of manufacturers' 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 additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability; • expansion of the entities eligible for discounts under the 340B drug pricing program; • new requirements to annually report to CMS certain data on payments and other transfers of value to physicians and teaching hospitals; • a requirement to annually report drug samples that manufacturers and distributors provide to physicians; 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 a number of significant changes to the ACA and its implementation, as well as judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. ~~Prior to the Supreme Court' s decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.~~ In addition, other legislative changes have been proposed and adopted since the ACA was enacted. **For example, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. Previously, the Medicaid rebate was capped at 100 % of a drug' s average manufacturer price, or AMP. Moreover, the federal government and the individual states in the United States have become increasingly active in developing proposals, passing legislation and implementing regulations designed to control drug pricing, including price or patient reimbursement constraints, discounts, formulary flexibility, marketing cost disclosure, drug price increase reporting, and other transparency measures.** These ~~changes include aggregate~~ **types of initiatives may result in additional** reductions ~~to~~ **in** Medicare **, Medicaid, and** ~~payments to providers pursuant to the~~ **other** ~~Budget Control~~ **healthcare funding, and may otherwise affect the prices we may obtain for FUROSCIX or the frequency with which FUROSCIX is prescribed or used. Most significantly, in August 2022, the Inflation Reduction** Act of **2022 (IRA) was signed into law. This** ~~2011, which began in 2013, and due to subsequent legislative amendments to the~~ statute ~~, will remain in effect through 2032. The American Taxpayer Relief Act~~ **marks the most**

significant action by Congress with respect to the pharmaceutical industry since adoption of **the ACA in** ~~2012~~ **2010** ~~,~~ **.** ~~among~~ **Among** other things, ~~further reduced~~ **the IRA requires manufacturers of certain drugs to engage in price negotiations with** Medicare ~~payments to several providers~~ , ~~including hospitals~~ **with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B** and ~~cancer treatment centers, and~~ **Medicare Part D to penalize price** ~~increased~~ **increases that outpace inflation (first due in 2023); redesigns** the ~~statute of limitations period~~ **Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new manufacturer discount program (beginning in 2025). CMS has published the negotiated prices** for the ~~government~~ **initial ten drugs, which will first be effective in 2026, and has published the list of the subsequent 15 drugs that will be subject** to ~~recover overpayments~~ **negotiation. The IRA permits the Secretary of the Department of Health and Human Services (HHS)** to ~~providers from~~ **implement many of** ~~three~~ **these provisions through guidance, as opposed** to ~~five~~ **regulation, for the initial** years **. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, but is likely to be significant** . These laws and similar future initiatives may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for FUROSCIX or our product candidates, if approved, and, accordingly, our financial operations. There also has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U. S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In March 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning January 1, 2024. The rebate was previously capped at 100 % of a drug ' s average manufacturer price. In August 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (~~beginning in~~ **which began on January 1,** 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August ~~29~~ **15** , ~~2023~~ **2024** , HHS announced the ~~list of~~ **agreed- upon prices for** the first ten drugs that **are** ~~will be~~ subject to price negotiations, ~~although~~ **which take effect in January 2026. HHS will select up to fifteen additional products covered under Part D for negotiation in 2025. Each year thereafter, more Part B and Part D products will become subject to** the **HHS** ~~Medicare drug~~ price negotiation **program, although the** program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated, or the impact of the IRA on our business. In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. For the 2018 and 2019 fiscal years, CMS altered the reimbursement formula from Average Sale Price, or ASP, plus 6 percent to ASP minus 22. 5 percent on specified covered outpatient drugs, or SCODs, but did so without issuing a formal notice of proposed rulemaking, which was subsequently challenged in court. In June 2022, the U. S. Supreme Court held that although the Department of Health and Human Services, or HHS, has authority to set reimbursement rates based on average price and discretion to " adjust " the price up or down, HHS may not vary the reimbursement rates by hospital group unless it conducts a survey of hospitals' acquisition costs. Accordingly, the U. S. Supreme Court held that HHS' s changes to the 2018 and 2019 reimbursement rates for 340B hospitals were unlawful. Based on the foregoing, CMS issued a final rule, effective January 1, 2023, pursuant to which CMS pays 340B hospitals under Medicare Part B for certain outpatient drugs at the drug' s ASP, plus 6 %, the same rate used for non- 340B hospitals. It is unclear how future changes to the payment methodology may affect pharmaceutical manufacturers and hospitals who purchase their products now and 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 **these and** other healthcare reform measures **that** may be adopted in the future ~~,~~ **may** result in ~~additional reductions in Medicare and other healthcare funding,~~ more rigorous coverage **and payment** criteria ~~, new payment methodologies~~ and **in** additional downward pressure on the price that we receive for any approved ~~product~~ **drug** . Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private ~~payers~~ **payors** . The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our **drugs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare** products **and services, which could result in reduced demand for our product candidates or additional pricing pressures. In addition, new and changing laws, regulations, executive orders and other governmental actions may also create uncertainty about how laws and regulations will be interpreted and applied. Regulatory changes and other actions that materially affect our business may be announced with little or no advance notice, and we may be unable to effectively mitigate all adverse impacts from such measures. We cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition. If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in which we participate, we could be subject to additional**

reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Medicaid is a joint federal and state program administered by the states for low income and disabled beneficiaries. We participate in and have certain price reporting obligations under the Medicaid Drug Rebate Program, or the MDRP, as a condition of having covered outpatient drugs payable under Medicaid and, if applicable, under Medicare Part B. The MDRP requires us to pay a rebate to state Medicaid programs every quarter for each unit of our covered outpatient drugs dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. The rebate is based on pricing data that we must report on a monthly and quarterly basis to the Centers for Medicare & Medicaid Services, or CMS, the federal agency that administers the MDRP and other governmental healthcare programs. These data include the average manufacturer price (AMP) for each drug and, in the case of innovator products, the best price, which in general represents the lowest price available from the manufacturer to certain entities in the U. S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. The Medicaid rebate consists of two components, the basic rebate and the additional rebate, which is triggered if the AMP for a drug increases faster than inflation. If we become aware that our MDRP government price reporting submission for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. If we fail to provide information timely or are found to have knowingly submitted false information to the government, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP. In the event that CMS terminates our rebate agreement pursuant to which we participate in the MDRP, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs. Our failure to comply with our MDRP price reporting and rebate payment obligations could negatively impact our financial results. The IRA imposes rebates under Medicare Part B and Medicare Part D that are triggered by price increases that outpace inflation (first due in 2023), as described under the risk factor " Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to commercialize FUROSCIX and may adversely affect the prices we may obtain and may have a negative impact on our business and results of operations, " above. The Medicare Part D rebate will be calculated on the basis of the AMP figures we report pursuant to the MDRP. Federal law requires that any company that participates in the MDRP also participate in the Public Health Service' s 340B drug pricing program in order for federal funds to be available for the manufacturer' s drugs under Medicaid and, if applicable, Medicare Part B. We participate in the 340B program, which is administered by the Health Resources and Services Administration, or HRSA, and requires us to charge statutorily defined covered entities no more than the 340B " ceiling price " for our covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low- income patients. The 340B ceiling price is calculated using a statutory formula based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes those prices to 340B covered entities. In addition, HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B- eligible drugs. HRSA has also finalized a revised regulation implementing an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs. Our failure to comply 340B program requirements could negatively impact our financial results. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under legislation or regulation could affect our 340B ceiling price calculations and also negatively impact our financial results. In order for FUROSCIX or any product candidates, if approved, to be paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we also participate in the U. S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. As part of this program, we are required to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (VA, U. S. Department of Defense, or DOD, Public Health Service, and U. S. Coast Guard). The FCP is based on the Non- Federal Average Manufacturer Price, or Non- FAMP, which we must calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non- FAMP filing can subject a manufacturer to significant civil monetary penalties for each item of false information. The FSS pricing and contracting obligations also contain extensive disclosure and certification requirements. We also participate in the Tricare Retail Pharmacy program, under which we are required to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non- FAMP and FCP. We are required to list our innovator products on a Tricare Agreement in order for them to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and / or to identify contract overcharges could result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and

growth prospects. Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation. Requirements of pharmaceutical manufacturers under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements, including the untimely, inaccurate, or incomplete reporting of drug pricing information. Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. CMS, the Department of Health & Human Services Office of Inspector General, and other governmental agencies have pursued manufacturers that were alleged to have failed to report these data to the government in a timely or accurate manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that any submissions we are required to make under the MDRP, the 340B program, the VA / FSS program, the Tricare Retail Pharmacy Program, and other governmental drug pricing programs will not be found to be incomplete or incorrect . Our relationships with customers and payers will be subject to applicable anti- kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings. Healthcare providers, including physicians, and third- party payers will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with principal investigators, healthcare professionals, consultants, third- party payers and customers, if any, will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws and regulations may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. The laws that will affect our operations include, but are not limited to, the following: • the federal Anti- Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation; • False claims laws, which prohibit anyone from knowingly and willfully presenting or causing to be presented for payment to third- party payers, including government payers, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Cases have been brought under false claims laws alleging that off- label promotion of pharmaceutical products or the provision of kickbacks has resulted in the submission of false claims to governmental healthcare programs. In addition, the government may assert that a claim, including items or services resulting from a violation of the federal Anti- Kickback Statute, constitutes a false or fraudulent claim for purposes of the false claims laws. Further, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act; • the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits persons or entities from knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation; • federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows, or should know, it is likely to influence the beneficiary' s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies; • federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; • the federal physician sunshine requirements under ACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U. S. Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non- physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; • 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 payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and • European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that our business practices, including our arrangements with physicians and other healthcare providers, some of whom received stock options as compensation for services provided, may be subject to challenge under current or future statutes, regulations, agency guidance or case law involving applicable fraud

and abuse or other healthcare laws and regulations. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm, and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time- consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition. The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition. In the U. S., the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder, or collectively HIPAA, imposes privacy, security and breach notification obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. We may obtain health information from third parties (including healthcare providers and research institutions from which we obtain patient health data) that are subject to privacy and security requirements under HIPAA. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA- covered healthcare provider or research institution that has not satisfied HIPAA' s requirements for disclosure of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health- related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act, or collectively, the CCPA, requires covered businesses that process the personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business' s collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information, and enter into specific contractual provisions with service providers that process California resident personal information on the business' s behalf. Similar laws have been passed in other states and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Furthermore, the Federal Trade Commission, or FTC, also has authority to initiate enforcement actions against entities that make deceptive statements about privacy and data sharing in privacy policies, fail to limit third- party use of personal health information, fail to implement policies to protect personal health information or engage in other unfair practices that harm customers or that may violate Section 5 (a) of the FTC Act. According to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the FTC Act. The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. The FTC and many state Attorneys General also continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. These consumer protection laws are increasingly being applied by FTC and state Attorneys General to regulate the collection, use, storage, and disclosure of personal or personally identifiable information, through websites or otherwise, and to regulate the presentation of website content. Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being

developed, reviewed, approved or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies ~~, such as the EMA following its relocation to Amsterdam and resulting staff changes,~~ may also slow the time necessary for new drugs, medical devices and biologics or modifications to approved drugs, and biologics to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, **in recent** ~~over the last several~~ years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. **There currently also exists significant uncertainty regarding staffing- levels at the FDA.** Separately, in response to the global COVID- 19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points ~~. Even though the FDA has since resumed standard inspection operations, any resurgence of the virus or emergence of new variants may lead to inspectional or administrative delays~~ . If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Risks Related to Our Intellectual Property Risks Related to Protecting our Intellectual Property Our success depends on our ability to protect our intellectual property and proprietary technology, as well as the ability of our collaborators to protect their intellectual property and proprietary technology. Our success depends in large part on our ability to obtain and maintain patent protection and trade secret protection in the United States and other countries with respect to our proprietary products and product candidates. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel products and product candidates that are important to our business; we also may license or purchase patent applications filed by others. The patent application and approval process is expensive and time- consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Agreements through which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented and may not be able to secure, maintain, or successfully enforce necessary or desirable patent protection ~~from~~ **of** those patent rights. We have not had and do not have primary control over patent prosecution and maintenance for certain of the patents and patent applications we license, and therefore cannot guarantee that these patents and applications will be prosecuted or maintained in a manner consistent with the best interests of our business. ~~We are reliant on patents and patent applications that we license for our product candidates and failure~~ **Failure** by owners of this intellectual property to enforce claims could have a negative impact on our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. If the scope of the patent protection we or our licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our licensed patents have, or that any of our pending licensed patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future products and product candidates or otherwise provide any competitive advantage, nor can we assure you that our licenses are or will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our licensed patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our products and product candidates. In addition, the patent portfolio licensed to us is, or may be, licensed to third parties, such as outside our field, and such third parties may have certain enforcement rights. Thus, patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against another licensee or in administrative proceedings brought by or against another licensee in response to such litigation or for other reasons. Even if they are unchallenged, our owned and licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our or our licensors' patents by developing similar or alternative technologies or therapeutics in a non- infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and / or a device that falls outside the scope of our patent protection or license rights. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our products and product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our products and product candidates could be negatively affected, which would harm our business. Similar risks would apply to any patents or patent applications that we may own or in- license in the future. We, or any future partners, collaborators, or

licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees, or licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees, or licensors, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and / or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and formulations commonly involves complex legal and factual questions, which ~~has~~ **have** in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third- party preissuance submission of prior art to the USPTO or to other patent offices around the world. Patent applications are generally maintained in confidence until publication. In the United States, for example, patent applications are typically maintained in secrecy for up to 18 months after their filing date. Similarly, publication of discoveries in scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we were the first to file patent applications on our products and product candidates. Any of the foregoing could harm our competitive position, business, financial condition, results of operations, and prospects. Alternately or additionally, we may become involved in post-grant review procedures, oppositions, ~~derivations~~ **derivation** proceedings, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such ~~challenges~~ **proceedings** may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Pending and future patent applications may not result in patents being issued which protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our products and product candidates by obtaining and defending patents. These risks and uncertainties include the following: • the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case; • patent applications may not result in any patents being issued; • patents that may be issued or in- licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage; • our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates; • there may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and • countries other than the United States may have patent laws less favorable to patentees than those upheld by U. S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates in such countries. Issued patents that we have or may obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our or our licensors' patents by developing similar or alternative technologies or products in a non- infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting ANDAs to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non- infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Pursuant to the terms of potential license agreements with

third parties, some of our third- party licensors may have the right, but not the obligation in certain circumstances to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors, and cannot guarantee that we would receive it and on what terms. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. If we cannot obtain patent protection, or enforce existing or future patents against third parties, our competitive position and our financial condition could suffer. In addition, we rely on the protection of our trade secrets and proprietary know- how. Although we have taken steps to protect our trade secrets and unpatented know- how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and there is a risk that third parties may still obtain this information or may come upon this or similar information independently. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know- how, our business may be harmed. It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection. Our commercial success will depend, in part, on obtaining and maintaining patent protection and trade secret protection for the formulations and compounds of our products and product candidates, the methods used to manufacture them, and associated methods of treatment as well as on successfully defending these patents against potential third- party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities. The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. We have not conducted **extensive** searches for third- party publications, patents and other information that may affect the patentability of claims in our various patent applications and patents, so we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, in our licensed patents or patent applications or in third- party patents. We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our product candidates and / or materially harm our business. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: • we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs; • it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent (s) will not: (a) be sufficient to protect our technology, (b) provide us with a basis for commercially viable products or (c) provide us with any competitive advantages; • we may not be the first to make the inventions covered by each of our patents and pending patent applications; • we may not be the first to file patent applications for these inventions; • if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under U. S. or foreign laws; or • if issued, the patents under which we hold rights may not be valid or enforceable. In addition, to the extent that we are unable to obtain and maintain patent protection for one of our product candidates or in the event that such patent protection expires, it may no longer be cost- effective to extend our portfolio by pursuing additional development of a product candidate for follow- on indications. We also may rely on trade secrets to protect our technologies or product candidates, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, there is a risk that our employees, consultants, contractors, outside scientific collaborators and other advisers may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third- party entity illegally obtained and is using any of our trade secrets is expensive and time- consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know- how. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Under the terms of some of our licenses, we do not have the ability to maintain or prosecute patents in the portfolio, and must therefore rely on third parties to comply with these requirements. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate

amount of time and if we do not obtain protection under the Hatch- Waxman Act and similar non- U. S. legislation for extending the term of patents covering each of our products and product candidates, our business may be materially harmed. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States, if available, and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 (or Hatch- Waxman Act) permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States, including the Leahy- Smith America Invents Act, or the America Invents Act, could increase those uncertainties and costs. The America Invents Act was signed into law on September 16, 2011, and many of the substantive changes became effective on March 16, 2013. The America Invents Act reforms United States patent law in part by changing the U. S. patent system from a " first- to- invent " system to a " first- inventor- to- file " system, expanding the definition of prior art, and developing a post- grant review system. This legislation changes United States patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 16, 2013. Further, the America Invents Act created new procedures to challenge the validity of issued patents in the United States, including post- grant review and inter partes review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents. For a patent with an effective filing date of March 16, 2013 or later, a petition for post- grant review can be filed by a third party in a nine month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for inter partes review can be filed after the nine month period for filing a post- grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post- grant review proceedings can be brought on any ground of invalidity, whereas inter partes review proceedings can only raise an invalidity challenge based on published prior art including patents. In these adversarial actions, the USPTO reviews patent claims without the presumption of validity afforded to U. S. patents in lawsuits in U. S. federal courts and uses a lower burden of proof than used in litigation in U. S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U. S. patent invalidated in a USPTO post- grant review or inter partes review proceeding than invalidated in litigation in a U. S. federal court. If any of our or our licensors' patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent rights to us. Depending on future actions by the U. S. Congress, the U. S. courts, the USPTO and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, a European Unified Patent Court (UPC) came into force during 2023. The UPC is a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time and may adversely affect our ability to enforce our European patents or defend the validity thereof. We may decide to opt out our European patents and patent applications from the UPC. If certain formalities and requirements are not met, however, our European patents and patent applications could be challenged for non- compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC. If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be negatively impacted and our business would be harmed. In addition to the protection afforded by patents, we also rely on trade secret protection for certain aspects of our intellectual property. We seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. There is a risk that any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating such trade secrets. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed. If our trademarks and trade names are not adequately protected, then we may not be able to build name

recognition in our marks of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and / or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. A NDA submitted under 505 (b) (2) may subject us to a patent infringement lawsuit that would delay or prevent product candidate review or approval. Section 505 (b) (2) permits the submission of a NDA where at least some of the information required for approval comes from preclinical studies and / or clinical trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. A NDA under 505 (b) (2) would enable us to reference published literature and / or the FDA' s previous findings of safety and effectiveness for a previously approved drug. For NDAs submitted under section 505 (b) (2), the patent certification and related provisions of the Hatch- Waxman Act apply. Accordingly, if we rely for approval on the safety or effectiveness information for a previously approved drug, referred to as a listed drug, we will be required to include patent certifications in the 505 (b) (2) NDA regarding any patents covering the listed drug. If there are patents listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for the listed drug, and we seek to obtain approval prior to the expiration of one or more of those patents, we will be required to submit a Paragraph IV certification indicating our belief that the relevant patents are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505 (b) (2) NDA. Otherwise, a 505 (b) (2) application cannot be approved by the FDA until the expiration of any patents listed in the Orange Book for the listed drug. In addition, a 505 (b) (2) application will not be approved until any non- patent exclusivity listed in the Orange Book for the listed drug, or for any other drug with the same, protected conditions of approval as the product candidate, has expired. These factors, among others, may limit our ability to gain approval of or successfully commercialize our product candidates. Risks Related to Intellectual Property Claims or Litigation Our drug development strategy relies heavily upon the 505 (b) (2) regulatory approval pathway, which requires us to certify that we do not infringe upon third- party patents covering approved drugs that we rely upon for approval if we want to obtain approval prior to patent expiry. Such certifications typically result in third- party claims of intellectual property infringement, the defense of which would be costly and time consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business. Our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505 (b) (2) regulatory approval pathway for the approval of our product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the Orange Book for the listed drug; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. We can avoid certifying to a method- of- use patent if we do not seek approval of the patented condition of use. If we certify to the FDA that a patent is invalid or not infringed, or a Paragraph IV certification, a notice of the Paragraph IV certification must also be sent to the patent owner and NDA holder shortly after our 505 (b) (2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit against us asserting infringement of the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our 505 (b) (2) application until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45- day period, our application will not be subject to the 30- month stay. However, even if the third party does not sue within the 45- day time limit, thereby invoking the 30- month stay, it may still challenge our right to market our product upon FDA approval; therefore, some risk of an infringement suit remains even after the expiry of the 45- day limit. We may not be able to enforce our intellectual property rights throughout the world. Filing, prosecuting, enforcing and defending patents on our products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products and product candidates. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection

to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Agreements through which we license patent rights may not give us sufficient rights to permit us to pursue enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents (or control of enforcement or defense) of such patent rights in all relevant jurisdictions as requirements may vary. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Others may claim an ownership interest in our intellectual property which could expose us to litigation and have a significant adverse effect on our prospects. A third party may claim an ownership interest in one or more of our or our licensors' patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and / or enjoin clinical testing, manufacturing and marketing of the affected product or products. While we are presently unaware of any claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources, and cause a significant diversion of effort by our technical and management personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross- licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product candidate, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights, Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates. Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may have U. S. and non- U. S. issued patents and pending patent applications relating to compounds, formulations, methods of manufacturing compounds and / or formulations, and / or methods of use for the treatment of the disease indications for which we are developing our product candidates. If any third- party patents or patent applications are found to cover our products or product candidates or their methods of use or manufacture, we may not be free to manufacture or market our product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all. There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates, including interference and post- grant proceedings before the USPTO. There may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the formulations, use or manufacture of our product candidates. We cannot guarantee that any of our patent analyses including, but not limited to, the scope of patent claims or the expiration of relevant patents are complete or thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our products and product candidates in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products or product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our products or product candidates, or methods of use or of making either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If we are found to infringe a third party' s intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product or product candidate. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product or product candidate. However, we may not be able to obtain any required

license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally, it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our products or product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Many of our current and former employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non- disclosure and non- competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology, products or product candidates. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful. Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are unenforceable, that the alleged infringing mark does not infringe our trademark rights, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this last instance, we could ultimately be forced to cease use of such trademarks. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Additionally, for certain of our in- licensed patent rights, we do not have the right to bring suit for infringement and must rely on third parties to enforce these rights for us. If we cannot or choose not to take action against those we believe infringe our intellectual property rights, we may have difficulty competing in certain markets where such potential infringers conduct their business, and our commercialization efforts may suffer as a result. Risks Related to Our Reliance on Third Parties Risks Related to Third Party Performance Use of third parties to manufacture our products and product candidates may increase the risk that we will not have sufficient quantities of our product candidates, products, or necessary quantities at an acceptable cost. We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our products and product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely on third parties for supply of the active pharmaceutical ingredients, or API, in our products and product candidates, and our furosemide formulation, as well as the device components of our drug- device combination products and product candidates. Our current strategy is to outsource all manufacturing of our product candidates and products to third parties. We currently engage third-party manufacturers to manufacture FUROSCIX and related supplies and packaging. For example, we have engaged a third-party manufacturer for the manufacture of the furosemide formulation used in FUROSCIX and we have engaged a third party

designer and manufacturer to develop and manufacture the on- body infusor for FUROSCIX. There is no guarantee that we can maintain our relationships with these manufacturers and we may incur added costs and delays in identifying and qualifying any replacements for such manufacturers. There is no assurance that we will be able to timely secure further needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to commercialize FUROSCIX. There may be difficulties and delays in obtaining sufficient commercial quantities of FUROSCIX and the costs of manufacturing could be prohibitive. Beyond FUROSCIX, third parties also manufacture the materials that we require for the development of our product candidates, and our reliance on these manufacturers for these activities carries similar risks as our reliance on third- party manufacturers in connection with FUROSCIX. Reliance on third- party manufacturers entails additional risks, including: • reliance on third parties for manufacturing process development, regulatory compliance and quality assurance; • limitations on supply availability resulting from capacity and scheduling constraints of third parties; • the possible breach of manufacturing agreements by third parties because of factors beyond our control; and • the possible termination or non- renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us. If we do not maintain our key manufacturing relationships or if our third- party manufactures fail to comply with applicable regulations, we may need to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our product candidates. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities. If any third- party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different third- party manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our product supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original third- party manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back- up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third- party manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations, and may need to obtain prior FDA approval with respect to any manufacturing changes for any approved products. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another foreign regulatory authority. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third- party manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently. This would increase our reliance on such third- party manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our products and product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Our approved product, FUROSCIX, is a drug- device combination product that is regulated under the drug regulations of the FDA based on its primary mode of action as a drug. Third- party manufacturers may not be able to comply with the cGMP requirements applicable to drug- device combination products, including applicable provisions of the FDA' s drug cGMP regulations, device cGMP requirements embodied in the QSR or similar regulatory requirements outside the United States. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs and QSR requirements or comparable foreign regulatory requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other foreign regulatory authorities, they will not be able to secure and / or maintain regulatory approval for the use of their manufacturing facilities for our products. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could cause significant delays in our operating timelines and would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP and QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval. The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with applicable cGMPs and QSR requirements and comparable foreign regulatory requirements. Contract manufacturers may face manufacturing or quality control problems causing drug substance or device component production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP or QSR requirements or comparable foreign regulatory requirements. Any failure to comply with cGMP or QSR requirements or other FDA and

comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval. Separately, in February 2024, the FDA issued a final rule to amend and replace the QSR to align more closely with the International Organization for Standardization standards. Specifically, this final rule, which the FDA currently expects to go into effect on February 2, 2026, establishes the " Quality Management System Regulation, " (QMSR), which among other things, incorporates by reference the quality management system requirements of ISO 13485: 2016. Although the FDA has stated that the standards contained in ISO 13485: 2106 are substantially similar to those set forth in the QSR, it is unclear the extent to which this final rule, once effective, could impose additional or different regulatory requirements on us or our contract manufacturers that could increase the costs of compliance or otherwise negatively affect our business. If we or our contract manufacturers are unable to comply with the QMSR, once effective, such failures could have an adverse effect on our business, financial condition and results of operations. We rely on third parties to conduct our preclinical studies and clinical trials. If they do not perform satisfactorily or fail to meet expected deadlines, our business could be harmed. We do not independently conduct clinical trials of any of our product candidates. We rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct these clinical trials and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. Any of these third parties may terminate their engagements with us under certain circumstances. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, there is a natural transition period when a new CRO begins work. As a result, delays would likely occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects. Further, although our reliance on these third parties for clinical development activities limits our control over these activities, we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. For example, notwithstanding the obligations of a CRO for a trial of one of our product candidates, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and foreign regulatory authorities require us to comply with standards, commonly referred to as Good Clinical Practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and IRBs. Similar requirements apply in other jurisdictions, such as the EU. If we or our third- party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our product candidates, which would delay the marketing approval process. We cannot be certain that, upon inspection, the FDA or comparable foreign regulatory authorities will determine that any of our clinical trials comply with GCPs. We are also required to register clinical trials and post the results of completed clinical trials on a government- sponsored database, ClinicalTrials. gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed. Risks Related to Third Party Contracts We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations. In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to our commercial agreements, we indemnify our vendors from any third- party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage and does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected. We expect to seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. We expect to seek one or more collaborators for the development and commercialization of one or more of our product candidates. For example, we started collaborating with West **Pharmaceutical Services, Inc.** in 2019 for development of the FUROSCIX infusor. Likely collaborators may include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain marketing approval for product candidates from foreign regulatory authorities, we intend to

enter into strategic relationships with international biotechnology or pharmaceutical companies for the commercialization of such product candidates outside of the United States. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. Collaborations are complex and time- consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. Risks Related to Employee Matters, Managing Growth and Business Operations We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations. We expect to continue to increase our number of employees and the scope of our operations. In particular, we will need to continue transitioning from a research and development company to a commercial company. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from their day- to- day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, and give rise to operational mistakes, loss of business and commercial opportunities, loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. Many of our suppliers and collaborative and clinical trial relationships are located outside the United States, and we may in the future seek to hire employees located outside of the United States. Accordingly, our business may become subject to economic, political, regulatory and other risks associated with international operations, such as compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, workforce uncertainty in countries where labor unrest is more common than in the United States, as well as difficulties associated with staffing and managing international operations, including differing labor relations. Any of these factors could materially affect our business, financial condition and results of operations. Our future financial performance, our ability to commercialize FUROSCIX and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company. We depend heavily on our executive officers, directors, and principal consultants and the loss of their services would materially harm our business. Our success depends, and will likely continue to depend, upon our ability to hire, retain the services of our current executive officers, directors, principal consultants and others. In addition, we have established relationships with universities and research institutions which have historically provided, and continue to provide, us with access to research laboratories, clinical trials, facilities and patients. Our ability to compete in the biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on our executive leadership team. We have employment agreements with these individuals but any individual may terminate his or her employment with us at any time. The loss of their services might impede the achievement of our research, development and commercialization objectives. We also do not have any key- person life insurance on any of these key employees. Departed personnel have sought to compete with us historically and may continue to do so in the future. Furthermore, replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Additionally, failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel. We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified

personnel, our ability to develop and commercialize our products and product candidates will be limited. Our company lacks experience commercializing products, which may have a material adverse effect on our business. We continue to transition from a company with a development focus to a company capable of supporting commercial activities. We completed building our initial sales force and began the commercial launch of FUROSCIX in February 2023. Since FUROSCIX is our first commercial product approved, we have not yet demonstrated ~~an~~ **long- term** ability to commercialize a product candidate or to obtain marketing approval for a product candidate outside of the U. S. Therefore, our clinical development, and commercialization processes and our regulatory approval process in the U. S. or countries outside of the U. S. may involve more inherent risk, take longer, and cost more than it would if we were a company with a more significant operating history and had experience obtaining approval and marketing approval for and commercializing a product candidate. Our employees, independent contractors, consultants, collaborators and contract research organizations may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation. We are exposed to the risk that our employees, independent contractors, consultants, collaborators, contract research organizations, principal investigators, suppliers and vendors may engage in fraud or other misconduct, including intentional, reckless and / or negligent conduct that fails to comply with FDA regulations or similar regulations of comparable non- U. S. regulatory authorities, to provide true, complete and accurate information to the FDA or comparable non-U. S. regulatory authorities, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U. S. regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to us. Such misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics to aid our directors, officers, employees and certain designated agents in making ethical and legal decisions when conducting business on our behalf and performing their day- to- day duties. However, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Additionally, we are subject to the risk that a private person or governmental agency could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. Risks Related to Business Operations and Growth We expect to expand our organization and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug manufacturing, regulatory affairs and sales, marketing and distribution, as well as to support our public company operations. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Moreover, our expected growth could require us to relocate to a different geographic area of the country. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the commercialization and development of FUROSCIX or additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our products and product candidates. We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards ~~. As of December 31, 2023, we had federal net operating loss carryforwards of $ 17. 5 million, which expire at various dates through 2037, and $ 127. 3 million, which may be carried forward indefinitely. At December 31, 2023, we had available state net operating loss carryforwards of $ 147. 1 million, which expire at various dates through 2043 and $ 1. 8 million, which may be carried forward indefinitely. If not utilized, the net operating loss carryforwards will expire. At December 31, 2023, we had federal and state research and development tax credit carryforwards of $ 3. 9 million and $ 1. 0 million, respectively. If not utilized, the research and development credits expire at various dates through 2043~~ . Our ability to use our U. S. federal and state net operating loss and tax credit carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 % **cumulative** change, by value, in its equity ownership **by certain significant shareholders** over a **rolling** three- year period, the corporation' s ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes to offset its post- change income may be limited. In 2017 we experienced an ownership change that we believe under Section 382 of the Code will result in limitations in our ability to utilize net operating losses and credits. In addition, we may experience future ownership changes as a result of future offerings or other changes in ownership of our stock. As a result, the amount of the net operating loss and tax credit carryforwards presented in our consolidated financial statements could be limited and may expire unutilized. Our

business could be adversely impacted by climate change, extreme weather conditions and natural disasters. The intensifying effects of climate change present physical, liability, and transition risks with both macro and micro implications for companies and financial markets. There is increasing concern that a gradual increase in global average temperatures due to increased concentration of carbon dioxide and other greenhouse gases in the atmosphere are causing significant changes in weather patterns around the globe and an increase in the frequency and severity of natural disasters. Changes in weather patterns and an increased frequency, intensity and duration of extreme weather events (such as floods, droughts, wildfires and severe storms), whether as a result of climate change or otherwise, could, among other things, disrupt our operations, including by damaging or destroying our facilities or those of our suppliers or manufacturing partners, which may cause us to suffer losses and additional costs to maintain or resume operations or as a result of supply chain- related delays or cancellations, which could have an adverse impact on our business and results of operations. In addition, implementing changes to mitigate risks associated with such events may result in substantial short- and long- term additional operational expenses, which may materially affect our profitability. General Risk Factors Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity. We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, personal information of customers and our employees and contractors and clinical data **(** ~~, or~~ collectively ~~,~~ **"** Confidential Information **")** . It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information. Our information technology systems and those of our third- party service providers, strategic partners and other contractors or consultants are vulnerable to attack and damage or interruption from computer viruses and malware (e. g. ransomware), malicious code, misconfigurations, " bugs " or other vulnerabilities, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, and sophisticated nation- state and nation- state- supported actors. We have also outsourced elements of our information technology infrastructure, and as a result a number of third- party vendors may or could have access to our Confidential Information. Further, attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can also be no assurance that our and our service providers', strategic partners' and other contractors' or consultants' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our Confidential Information or other similar disruptions. If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of personal information, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws. We could also incur liability, including litigation exposure, penalties and fines, and we could become the subject of regulatory action or investigation. Our competitive position could be harmed and the further development and commercialization of our products and services could be delayed. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. For example, in February 2024, UnitedHealth Group announced that its Change Healthcare information technology systems were being taken offline for an undefined period, which has impacted and could continue to impact our operations, including the ability of third- party pharmacies to fill electronic prescriptions our clinicians may write for patients. We have observed a disruption in claims being processed resulting in delays in patients receiving shipments of FUROSCIX as a result of the Change Healthcare issue. Such failures or breaches of our third- party vendors' security measures, or our third-party vendors' inability to effectively resolve such failures or breaches in a timely manner, could adversely impact our financial results ~~, including our results for the quarter ending March 31, 2024~~ . Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products and product candidates. The risk that we may be sued on product liability claims is inherent in the commercialization of and development of drug formulation and device products. We face a risk of product liability exposure related to our marketed product and the testing of our product candidates in clinical trials. Product liability claims might be brought against us by consumers, healthcare providers or others coming into contact with our products and product candidates. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of one or more of our products which could adversely affect our stock price and our operations. We may become involved in litigation or other proceedings with third parties, which may be time consuming, costly and could result in delays in our development and commercialization efforts. Any disputes with

such third parties that lead to litigation or similar proceedings may result in us incurring legal expenses, as well as facing potential legal liability. Such disputes, litigation or other proceedings are also time consuming and may cause delays in our development and commercialization efforts. If we fail to resolve these disputes quickly and on favorable terms, our business, results of operations, and financial condition may be harmed. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, for example, severely diminished liquidity and credit availability, rising interest and inflation rates, **tariffs and trade wars,** crises involving banking and financial institutions, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets continue to deteriorate, or the United States enters a recession, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. In addition, there is a risk that one or more of our CROs, suppliers, CMOs, or other third- party providers may not survive an economic downturn or recession. As a result, our business, results of operations and price of our common stock may be adversely affected. Increased scrutiny of, and evolving expectations regarding, sustainability and environmental, social, and governance (" ESG ") matters could increase our costs, harm our reputation and adversely impact our financial results. Companies are facing increasing and evolving scrutiny related to ESG practices and disclosures **.** ~~from certain investors, government entities, customers, employees and other stakeholders~~ **Stakeholders** ~~or third parties~~ **' expectations continue to evolve; moreover, they are not uniform, and at times are conflicting** . **Addressing these expectations comes** ~~With~~ **with** ~~this increased focus~~ **inherent costs and complexity** , **and any failure** ~~public reporting regarding ESG practices is becoming more broadly expected, which could lead~~ to **successfully navigate** ~~increased scrutiny of our ESG practices or lack thereof. Such~~ **such matters** ~~increased scrutiny~~ may **adversely** result in increased costs, increased risk of litigation or reputational damage relating to our ESG practices or performance, enhanced compliance or disclosure obligations, or other adverse impacts on our business, financial condition or results of operations. While we may at times engage in voluntary initiatives (such as voluntary disclosures or goals), such initiatives may be costly and may not have the desired effect. **Any efforts to improve our ESG profile** ~~For~~ - **or respond** ~~example, we may commit~~ to ~~certain initiatives~~ **stakeholder expectations can be costly** and ~~we~~ may not ~~ultimately be able~~ **have the desired effect. Our ability** to achieve ~~such initiatives due~~ **any ESG objective is subject** to ~~cost~~ **numerous risks** , **many of which** ~~technological constraints or other factors that~~ are ~~within or~~ outside of our control ~~. Even if we achieve our initiatives, our actions may subsequently be determined to be insufficient by various stakeholders or other third parties~~ . If our ESG practices and reporting do not meet investor, regulator, customer, employee or other stakeholder or third party expectations, which continue to evolve, our brand, reputation and / or business relationships may be negatively impacted, and we may be subject to investor or regulator engagement regarding such matters. Certain market participants, including major institutional investors, use third- party benchmarks, ratings or scores to measure our ESG practices in making investment and voting decisions. Unfavorable ratings or scores of us or our industry may lead to negative investor sentiment and the diversion of investment to other companies or industries, which could have a negative impact on our stock price and our access to and cost of capital. As ESG best practices, reporting standards and disclosure requirements continue to develop, we may incur increasing costs related to ESG monitoring and reporting. In addition, new ESG rules and regulations have been adopted and may continue to be introduced in various states and other jurisdictions **. Such laws are complex and at times divergent, which may increase costs and complexity of compliance and any associated risks** . Our failure to comply with any applicable rules or regulations could lead to penalties and adversely impact our reputation, customer attraction and retention, access to capital and employee retention. Such ESG matters may also impact our suppliers, customers and business partners, which may augment or cause additional impacts on our business, financial condition or results of operations. Risks Related to Ownership of Our Common Stock The trading price of our common stock may be highly volatile and fluctuate substantially. Our stock price is likely to be highly volatile. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including: • regulatory actions with respect to our product candidates; • the pricing, reimbursement and commercialization of FUROSCIX and of other product candidates that may be approved; • regulatory actions with respect to our competitors' products and product candidates; • the success of existing or new competitive products or technologies; • announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; • the timing and results of clinical trials of our pipeline product candidates; • commencement or termination of collaborations for our development programs; • failure or discontinuation of any of our development programs; • results of clinical trials of product candidates of our competitors; • regulatory or legal developments in the United States and other countries; • developments or disputes concerning patent applications, issued patents or other proprietary rights, including proprietary rights that we in- license from third parties; • the recruitment or departure of key personnel; • the level of expenses related to any of our products or product candidates or clinical development programs; • the results of our efforts to develop additional product candidates or products; • actual or anticipated changes in estimates as to financial results or development timelines; • announcement or expectation of additional financing efforts; • sales of our common stock by us, our insiders or other stockholders; • variations in our financial results or those of companies that are perceived to be similar to us; • changes in estimates or recommendations by securities analysts, if any, that cover our stock; • changes in the structure of healthcare payment systems; • market conditions in the pharmaceutical and biotechnology sectors; • general economic, industry and market conditions; and • the other factors described in this " Risk Factors " section. Additionally, in the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. 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. Raising additional capital may cause

dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. We expect our expenses to increase in connection with our planned operations. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership percentages of all our stockholders may be diluted, and the terms of these securities could include liquidation or other preferences and anti- dilution protections that could adversely affect the rights of our stockholders. In addition, royalty- based financing or debt financing, **such as our Revenue Purchase and Sale Agreement,** if available, ~~may~~ **will** result in our relinquishing rights to valuable future revenue streams or fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day- to- day activities, which may adversely affect our management' s ability to oversee the commercialization of FUROSCIX and the development of our product candidates. If we raise additional funds through collaborations or marketing, distribution or licensing, or royalty- based financing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, products or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment. We have never declared nor paid cash dividends on our capital stock. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. In addition, the terms of any of our existing, and potentially future, debt or credit agreements will restrict or preclude us from paying dividends. For example, under our Credit Agreement with Oaktree, we are restricted from paying any dividends or making any distributions on account of our capital stock if we are in, or expected to be, in default. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future. Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions. Based upon shares outstanding as of December 31, ~~2023~~ **2024** , our executive officers and directors, combined with our stockholders who own more than 5 % of our outstanding common stock and their affiliates, in the aggregate, beneficially own shares representing approximately ~~54~~ **41** . ~~6~~ **8** % of our common stock. As a result, if these stockholders were to choose to act together, they would be able to ~~control~~ **significantly influence** all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would **exert significant influence over, and potentially** control **,** the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership ~~control~~ may: • delay, defer or prevent a change in control; • entrench our management or the board of directors; or • impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire. Some of these persons or entities may have interests that are different than those of other stockholders. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares were sold in our initial public offering and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors or they may want us to pursue strategies that deviate from the interests of other stockholders. We are a " smaller reporting company, " as defined in the Exchange Act, and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors. We are a " smaller reporting company " as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non- voting common stock held by non- affiliates is more than $ 250. 0 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $ 100. 0 million during the most recently completed fiscal year and our voting and non- voting common stock held by non- affiliates is more than $ 700. 0 million measured on the last business day of our second fiscal quarter, which we refer to as a low- revenue smaller reporting company. Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as a low- revenue smaller reporting company, which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as a smaller reporting company we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile and may decline. As a public company, we must comply with public company reporting and other obligations. Continued compliance with these requirements will increase our costs and require additional management resources, and do not ensure that we will be able to satisfy them. As a result of operating as a public company, compliance with the Sarbanes- Oxley Act of 2002, as well as other rules and regulations promulgated by the SEC and the Nasdaq Stock Market LLC, or Nasdaq, results in significant legal, accounting, administrative and other costs and expenses. The listing requirements of the Nasdaq Global Select Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to continue to devote a substantial amount of time to ensure that we continue to comply with all of these requirements. We are subject to Section 404 of the Sarbanes- Oxley Act of 2002, or Section 404, and

the related rules of the SEC that generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain a low- revenue smaller reporting company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not smaller reporting companies, including, but not limited to, not being required to comply with the auditor attestation requirement of Section 404. Once we are no longer a low- revenue smaller reporting company or, if before such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. ~~During~~ **We have in** the ~~course of~~ **past and may in the future identify a material weakness in our internal control over financial reporting. If we are unable to remediate any such material weakness, we may not be able to accurately** ~~our~~ **or** ~~review and testing of~~ **timely report our financial condition** ~~our~~ **or results of operations, which may adversely affect our business and stock price. For example, as previously disclosed in our Annual Report for the period ended December 31, 2023, in connection with the preparation of our financial statements for that period, management previously identified a material weakness related to the controls, processes and procedures over the fair value accounting associated with the embedded derivative liability in connection with the Oaktree Agreement. This material weakness has since been remediated; however, we cannot assure you that the measures we are taking will be sufficient to avoid the identification of additional material weaknesses in the future. Furthermore, if we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated, especially for so long as our independent registered public accounting firm is not required to provide an attestation report on the effectiveness of such** internal controls **over financial** ~~, we may identify deficiencies and be unable to remediate them before we must provide the required reports~~ **reporting . We** , as is the case in this Annual Report on Form 10- K, ~~due to the material weakness identified and described below. This material weakness in our internal control over financial reporting resulted in management being unable to conclude, and any additional material weakness in our internal control over financial reporting may in the future result in our management being unable to conclude, that our disclosure controls and procedures were effective for the applicable period. Furthermore, if we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated, especially for so long as our independent registered public accounting firm is not required to provide an attestation report on the effectiveness of such internal controls over financial reporting. We, as is the case in this Annual Report on Form 10- K,~~ or our independent registered public accounting firm, once we are no longer a lower- revenue small reporting company, may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to timely file accurate quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences ~~. We have identified a material weakness in our internal control over financial reporting. If we are unable to remediate this material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and stock price. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the financial statements will not be prevented or detected on a timely basis. In connection with the preparation of our financial statements for this Annual Report on Form 10- K, we identified a material weakness in our internal control over financial reporting related to our failure to maintain proper controls, processes and procedures over the fair value accounting associated with the embedded derivative liability, in connection with the Oaktree Agreement. See Item 7, " Management' s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources " for a description of the Oaktree Agreement. Specifically, the calculation performed by our third- party valuation specialist during the fourth quarter of the year ended December 31, 2023 as it relates to fair value accounting for the liability included errors resulting in an overstatement in the fair value of the liability. We made adjustments necessary to properly reflect the fair value of the derivative liability in the financial statements included in this Annual Report on Form 10- K for the period ended December 31, 2023. Although the material weakness identified above did not result in any changes to previously released financial results, our management concluded that these control deficiencies constitute a material weakness and that our internal control over financial reporting was not effective as of December 31, 2023. Our management, with the oversight of our audit committee, has initiated steps and plans to take additional measures to remediate the underlying causes of the material weakness, which we currently believe will be primarily through revising precision level of management review controls and gaining additional assurance regarding our outside service providers' quality control procedures. Although we plan to complete implementing the remediation plan as quickly as possible, we cannot at this time estimate how long it will take, and our initiatives may not prove to be successful in remediating this material weakness. The above remediations to our controls need to operate for a sufficient period of time so that management can conclude that our controls are operating effectively. As such, the material weakness will not be considered remediated until management has concluded through the implementation of these remediation measures and additional testing that these controls are effective. If our remedial measures are insufficient to address the material weakness, or if additional material weaknesses or significant deficiencies in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results. In addition, if we are unable to successfully remediate this material weakness and if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected and we may be unable to maintain compliance with applicable stock exchange listing requirements~~ . Future

sales of our common stock into the market could cause the market price of our common stock to decline significantly, even if our business is doing well. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Persons who were our stockholders prior to our IPO continue to hold a substantial number of shares of our common stock that many of them are now able to sell in the public market. If these pre- IPO shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Moreover, certain holders of securities issued prior to our IPO have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. **Future issuances of our common stock or the issuance of shares of common stock upon the exercise or conversion of securities that are exercisable or convertible into shares of common stock, such as our pre-funded warrants, or upon the exercise or vesting of incentive awards, may result in dilution for our stockholders. We have needed and anticipate we will need additional capital in the future to continue our planned operations. To the extent that 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. We also expect to issue common stock to employees, directors, and consultants pursuant to our equity incentive plans. If we sell common stock, convertible securities, or other equity securities in subsequent transactions, or common stock is issued pursuant to equity incentive plans, investors may be materially diluted. New investors in such subsequent transactions could gain rights, preferences, and privileges senior to those of holders of our common stock. As of December 31, 2024, we have outstanding pre- funded warrants to purchase 3, 405, 000 shares of common stock at an exercise price of $ 0. 001 per share, which may be paid by way of a cashless exercise, meaning that the holder may not pay a cash purchase price upon exercise, but instead would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the pre- funded warrant. Accordingly, we will not receive a significant amount, or potentially any, additional funds upon the exercise of the pre- funded warrants. To the extent such pre- funded warrants are exercised, additional shares of common stock will be issued for nominal or no additional consideration, which could result in substantial dilution to then existing holders of our common stock and will increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of the common stock, causing our stock price to decline.** If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. In the event one or more analysts downgrade our stock or change their opinion of our stock, our share price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. An active trading market for our common stock may not be sustainable. If an active trading market is not sustained, our ability to raise capital in the future may be impaired. **An** ~~We completed our initial public offering in November 2017. Prior to this time, there was no public market for our common stock. Although we have completed our initial public offering and shares of our common stock are listed and trading on the Nasdaq Global Select Market, an~~ active trading market for our shares **of common stock** may not be sustained. If an active market for our common stock is not sustained, it may be difficult for our stockholders to sell shares of our common stock without depressing the market price for the shares or at all. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration. Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management or hinder efforts to acquire a controlling interest in us. Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions: • establish a classified board of directors such that all members of the board are not elected at one time; • allow the authorized number of our directors to be changed only by resolution of our board of directors; • limit the manner in which stockholders can remove directors from the board; • establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings; • require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; • limit who may call a special meeting of stockholders; • authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a " poison pill " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and • require the approval of the holders of at least two- thirds of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers for our

common stock. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock. Our bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. Pursuant to our bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for any state law claim for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders; (3) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America are the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, or the rules and regulations promulgated thereunder, and of all suits in equity and actions at law brought to enforce any liability or duty created by the Securities Act or the rules and regulations thereunder. In addition, our bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our Common Stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U. S. federal securities laws and the rules and regulations thereunder. The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. While the Delaware Supreme Court and other states have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on us and / or our stockholders who assert that the provision is invalid or unenforceable. The Court of Chancery of the State of Delaware or the federal district courts of the United States of America may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.