Risk Factors Comparison 2025-03-27 to 2024-03-13 Form: 10-K

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Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Annual Report on Form 10- K, including the section of this Annual Report on Form 10- K titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and our consolidated financial statements and related notes, and in other documents that we file with the SEC, in evaluating our company and our business. ~~Investing in our securities involves a high degree of risk.~~ If any of the events described in the following risk factors and the risks described elsewhere in this Annual Report on Form 10- K actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected, and the trading price of our securities could decline. Our actual results could differ materially from those anticipated in the forward- looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10- K. **The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.** Risks Related to Product Development and Commercialization **Pursuant to our previously announced restructuring, we suspended development of our SPR720 oral program and have shifted our focus and resources to advancing the clinical development of our tebipenem HBr program, as well as other corporate activities. We have also discontinued development of SPR206. Consequently, our business and prospects are substantially dependent on our tebipenem program and our collaboration with GSK. If we fail to execute successfully on this re- prioritized strategic focus, our business and prospects may be materially adversely affected On October 29, 2024, we announced that we suspended development activities for our SPR720 oral program based on an interim analysis of the Phase 2a proof- of- concept study of SPR720 for the treatment of NTM- PD not meeting its primary endpoint. While the data showed antimicrobial activity associated with SPR720, the interim analysis did not show sufficient separation from placebo and highlighted potential dose limiting safety issues in subjects dosed at 1, 000 mg orally once daily, including three cases of reversible grade 3 hepatotoxicity. In evaluating the totality of both the efficacy and safety data, we have elected to suspend our current development program for SPR720 and continue to evaluate other potential paths forward as the remaining data are collected and analyzed. As a result, we have restructured our operations to focus on supporting the development of tebipenem HBr and other corporate activities while we continue to seek a pathway forward for SPR720. Further, in March 2025, we announced that we have discontinued development of SPR206. We believe this re- prioritized strategic focus is the best way to optimize our financial and other resources to advance our goal of developing and commercializing product candidates to address the unmet need for solutions to antibiotic resistant pathogens. However, there is no assurance that we will successfully execute this strategy. As described below, there are risks inherent in the clinical development process, especially for earlier- stage programs, and the regulatory path for SPR720 remains uncertain at this time. If we are unable to execute successfully on this re- prioritized strategic focus, our business and prospects may be materially adversely affected. As a result, we are currently substantially dependent on our tebipenem program and our collaboration with GSK. As described under " Business — Collaboration, License and Service Agreements — Tebipenem HBr Agreements ", GSK has the right to terminate the GSK License Agreement (1) at any time upon a specified number of days' notice, (2) upon a material breach by us or (3) upon a bankruptcy of Spero. Alternatively, in the case of a material breach by Spero, GSK may, in lieu of terminating the GSK License Agreement, elect to reduce any commercial milestone payments to Spero by 50 %. In addition, in such circumstance, GSK may assume the responsibility and expense of development of tebipenem HBr in the United States, in which case no development milestone payments would be payable to Spero (including unpaid installments of any earned milestone payments). In the case of a Change of Control of Spero, GSK similarly may, in lieu of terminating the GSK License Agreement, assume responsibility and expense of development of tebipenem HBr in the United States and no development milestones would be payable to Spero, as described above. Any termination of the GSK License Agreement or any failure to earn, or reduction in, milestone payments may materially adversely affect our business and prospects.** Our ability to realize the value of tebipenem HBr depends on ~~us~~ obtaining FDA approval. Even if such approval is obtained, the timeline of, and any requirements imposed as ~~of~~ part of, such approval may impact the attractiveness of eventual commercialization of tebipenem HBr through our partnership with GSK. We currently have no products approved for sale and have invested a significant portion of our efforts and financial resources in the development of tebipenem HBr as a product candidate for the treatment of bacterial infections causing cUTI. Our ability to realize the value of tebipenem HBr depends on the potential FDA approval, and the expected timeline and other requirements that would affect the attractiveness of eventual commercialization of tebipenem HBr through our partnership with GSK. Further, as part of any approval, the FDA could impose labeling requirements restricting the use of tebipenem HBr, which could reduce its commercial prospects, unless such requirements are subsequently modified to reduce such restrictions. If any of these outcomes occur, our business could be materially harmed. If our clinical trials fail to produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates. We may not commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA or in other countries without obtaining approvals from comparable foreign regulatory authorities, such as the EMA, and we may never receive such approvals. We must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain

these approvals. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. The clinical development of any of our product candidates is susceptible to the risk of failure inherent at any stage of drug development, including failure to demonstrate efficacy in a trial or across a broad population of patients, the occurrence of severe adverse events, failure to comply with protocols or applicable regulatory requirements, and determination by the FDA or any comparable foreign regulatory authority that a drug product is not approvable. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after promising results in earlier nonclinical studies or clinical trials. The results of preclinical and other nonclinical studies and / or early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. Notwithstanding any promising results in early nonclinical studies or clinical trials, we cannot be certain that we will not face similar setbacks. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we believe that the results of our clinical trials warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates. In some instances, there can be significant variability in safety and / or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants, among others. It is possible that even if one or more of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one of the factors listed or otherwise. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials, we may fail to detect toxicity of or intolerability of our product candidates or may determine that our product candidates are toxic or not well tolerated when that is not in fact the case. In the case of our clinical trials, results may differ on the basis of the type of bacteria with which patients are infected. We cannot make assurances that any clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. We may encounter unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent us from obtaining regulatory approval for any of our product candidates, including: • the FDA or other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials; • we may be delayed in or fail to reach agreement on acceptable terms with prospective 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; • clinical trials of our product candidates may produce unfavorable or inconclusive results; • we may decide, or regulators may cause us, to conduct additional clinical trials or abandon product development programs; • the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit suitable patients to participate in clinical trials; • our third- party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • the FDA or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • regulators or institutional review boards may require that we or our investigators suspend or terminate clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate; • the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third- party manufacturers with which we enter into agreements for clinical and commercial supplies; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards (“ IRBs ”) responsible for overseeing such trials, by the Data Safety Monitoring Board (“ DSMB ”) if any, for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug or changes in governmental regulations or administrative actions. If we are required to conduct additional clinical trials or other testing of any of our product candidates beyond the trials and testing that we contemplate, if we are unable to successfully complete clinical trials or other testing of our product candidates, if the results of these trials or tests are unfavorable or are only modestly favorable or if there are safety concerns associated with any of our product candidates, we may: • incur additional unplanned costs; • be delayed in obtaining marketing approval for our product candidates; • not obtain marketing approval at all; • obtain approval for indications or patient populations that are not as broad as intended or desired; • obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings; • be subject to additional post- marketing testing or other requirements; or • be required to remove the product from the market after obtaining marketing approval. Our failure to successfully initiate and complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business. Our product candidate development costs will also increase if we experience delays in testing or marketing approvals and we may be required to obtain additional funds to complete clinical trials. We cannot make assurances that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays also could shorten any periods during

which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of any of our product candidates. If we experience delays or difficulties in the enrollment of patients in clinical trials, clinical development activities could be delayed or otherwise adversely affected. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may not be able to initiate, continue or complete clinical trials of our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in clinical trials as required by the FDA or comparable foreign regulatory authorities, such as the EMA. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including: • the size and nature of the target patient population; • the severity of the disease under investigation; • the proximity of patients to clinical sites; • the patient eligibility criteria for participation in the clinical trial; • the design of the clinical trial; • **the availability of clinically evaluable patients; •** our ability to recruit clinical trial investigators with appropriate competencies and experience; • competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating; • our ability to obtain and maintain patient consents; and • the risk that participants enrolled in clinical trials will drop out of the trials before completion. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might 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, slow down or halt our product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of our company to decline and limit our ability to obtain additional financing if needed. Congress also recently amended the FDCA to require sponsors of a Phase 3 clinical trial, or other " pivotal study " of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. In the future, we will be required to submit a diversity action plan to the FDA by the time we submit a Phase 3 **clinical** trial, or pivotal study, protocol to the agency for review, unless we are able to obtain a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect the planning and timing of any future Phase 3 **clinical** trial for our product candidates ~~or what specific information FDA will expect in such plans~~ . However, initiation of such trials may be delayed if the FDA objects to our proposed diversity action plans for any future Phase 3 **clinical** trial for our product candidates, and we may experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan. Analyses of preliminary or interim data from our clinical 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. We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate through well- controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early- stage clinical trials does not mean that future larger registration clinical trials will be successful. This is because product candidates in later- stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and comparable foreign regulatory authorities despite having progressed through preclinical studies and early- stage clinical trials. Analyses of preliminary or interim data from our clinical studies are not necessarily predictive of analyses of final data. Analyses of preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change, as more patient data become available and we issue our final clinical study report. Preliminary or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, analyses of interim and preliminary data should be viewed with caution until the analyses of final data are available. Adverse differences between preliminary or interim data and final data could affect our planned clinical path for any of our product candidates we advance into clinical trials, including potentially increasing cost and / or causing delay in such development. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We therefore do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. Serious adverse events or undesirable side effects or other unexpected properties of any of our product candidates may be identified during development or after approval that could delay, prevent or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval. Serious adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, an IRB, or regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label, the imposition of distribution or use restrictions or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. If any of our other product candidates are associated with serious or unexpected adverse events or undesirable side effects, the FDA, the IRBs responsible for overseeing our studies, or a DSMB, could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment- related side effects could also affect patient recruitment or the ability

of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. If unexpected adverse events occur in any of our ongoing or planned clinical trials, we may need to abandon development of our product candidates, or limit development to lower doses or to certain uses or subpopulations in which the undesirable side effects or other unfavorable characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Undesirable side effects or other unexpected adverse events or properties of any of our other product candidates could arise or become known either during clinical development or, if approved, after the approved product has been marketed. If such an event occurs during development, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or could deny approval of our product candidates. If such an event occurs after such product candidates are approved, a number of potentially significant negative consequences may result, including: • regulatory authorities may withdraw or limit their approval of such product; • we may decide to or be required to recall a product or change the way such product is administered to patients; • regulatory authorities may require additional warnings on the label, such as a " black box " warning or a contraindication, or impose use restrictions; • regulatory authorities may require one or more post- market studies to monitor the safety and efficacy of the product; • we may be required to implement a REMS, which may include the creation of a medication guide outlining the risks of such side effects for distribution to patients or restrictions on distribution **or other elements**; • we could be sued and held liable for harm caused to patients exposed to or taking our product candidates; • our product may become less competitive; and • our reputation may suffer. We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our products and harm our business and results of operations. Even if a product candidate does obtain regulatory approval, it may never achieve the market acceptance by physicians, patients, hospitals, third- party payors and others in the medical community that is necessary for commercial success and the market opportunity may be smaller than we estimate. Even if we obtain FDA or other regulatory approvals and are able to launch any of our product candidates commercially, the approved product candidate may nonetheless fail to gain sufficient market acceptance among physicians, patients, hospitals (including pharmacy directors) and third- party payors and, ultimately, may not be commercially successful. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of coverage and reimbursement for existing therapies. If an approved product candidate does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of any product candidate for which we receive approval depends on a number of factors, including: • the efficacy and safety of the product candidate as demonstrated in clinical trials; • relative convenience and ease of administration; • the clinical indications for which the product candidate is approved; • the potential and perceived advantages and disadvantages of the product candidates, including cost and clinical benefit relative to alternative treatments; • the willingness of physicians to prescribe the product and of the target patient population to try new therapies; • the willingness of hospital pharmacy directors to purchase the product for their formularies; • acceptance by physicians, patients, operators of hospitals and treatment facilities and parties responsible for coverage and reimbursement of the product; • the availability of coverage and adequate reimbursement by third- party payors and government authorities; • the effectiveness of our sales and marketing efforts; • the strength of marketing and distribution support; • limitations or warnings, including distribution or use restrictions, contained in the product' s approved labeling or an approved REMS; • whether the product is designated under physician treatment guidelines as a first- line therapy or as a second- or third- line therapy for particular infections; • the approval of other new products for the same indications; • the timing of market introduction of the approved product as well as competitive products; • adverse publicity about the product or favorable publicity about competitive products; • the emergence of bacterial resistance to the product; and • the rate at which resistance to other drugs in the target infections grows. Any failure of any of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for marketing approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate. If we or our collaborators are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing any of our product candidates if such product candidates are approved. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource those functions to third parties. The development of sales, marketing and distribution capabilities will require substantial resources, will be time- consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution

capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we intend to target. If we or our collaborators are unable to establish a sales force and marketing and distribution capabilities, our operating results may be adversely affected. Factors that may inhibit our efforts to commercialize our products on our own include: • our inability to recruit and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. We intend to use collaborators to assist with the commercialization of any of our product candidates, including the GSK License Agreement for the development and commercialization of tebipenem HBr. As a result of entering into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us would likely be lower than if we were to directly market and sell products in those markets. Furthermore, we may be unsuccessful in entering into the necessary arrangements with third parties or may be unable to do so on terms that are favorable to us. In addition, we likely would have little control over such third parties, and any of them might fail to devote the necessary resources and attention to sell and market our products effectively. If we or our collaborators do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. We face substantial competition from other pharmaceutical and biotechnology companies and our operating results may suffer if we fail to compete effectively. The development and commercialization of new drug products is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to our product candidates that we may seek to develop and commercialize in the future. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of resistant infections. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than the product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive. There are a variety of available oral therapies marketed for the treatment of cUTIs that we would expect would compete with tebipenem HBr, if approved, such as Levaquin, Cipro and Bactrim. Many of the available therapies are well established and widely accepted by physicians, patients and third- party payors. Insurers and other third- party payors may also encourage the use of generic products, for example in the fluoroquinolone class. However, the susceptibility of urinary tract pathogens to the existing treatment alternatives is waning. If tebipenem HBr is approved, the pricing may be at a significant premium over other competitive products. This may make it difficult for tebipenem HBr to compete with these products. There are ~~also a number of oral product candidates in clinical development by third parties that are intended to treat cUTIs. One such product candidate is ceftibuten / clavulanate (" C- Scape") from Cipla Therapeutics, Inc. If our competitors obtain marketing approval from the FDA or comparable foreign regulatory authorities for their product candidates more rapidly than us, it could result in our competitors establishing a strong market position before we are able to enter the market. There are~~ several IV-administered products marketed for the treatment of infections resistant to first- line therapy for Gram- negative infections, including **Avycaz (** ceftazidime- avibactam ~~(" Avycaz")~~ from Allergan plc and Pfizer Inc., **Zerbaxa (** ceftolozane- tazobactam ~~(" Zerbaxa")~~ from Merck & Co., imipenem / cilastatin and **Recarbrio (** relebactam ~~(" Recarbrio")~~ from Merck & Co., **Zemdri (** plazomicin ~~(" Zemdri")~~ from Cipla Therapeutics, Inc., **Fetroja (** cefiderocol ~~(" Fetroja")~~ from Shionogi & Co. Ltd., **Xerava (** eravacycline ~~(" Xerava")~~ from **Innoviva** ~~Tetraphase Pharmaceuticals~~ , Inc. and **Vabomere (** meropenem- vaborbactam ~~(" Vabomere")~~ from Melinta Therapeutics, Inc **., and Exblifep (cefepime / enmetazobactam) from Allecra Therapeutics** . Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early **-** stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Even if we or our partners are able to commercialize any of our product candidates, the product may become subject to unfavorable pricing regulations, or third- party payor coverage and reimbursement policies that could harm our business. Marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which may negatively affect the revenues that we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. We currently expect that some of our product candidates, if approved, will be administered in a hospital inpatient setting. In the United States, governmental and other third-party payors generally reimburse hospitals a single bundled payment established on a prospective basis intended to cover all items and services provided to the patient during a single hospitalization. Hospitals bill third- party payors for all or a portion of

the fees associated with the patient' s hospitalization and bill patients for any deductibles or co- payments. Because there is typically no separate reimbursement for drugs administered in a hospital inpatient setting, some of our target customers may be unwilling to adopt our product candidates in light of the additional associated cost. If we are forced to lower the price we charge for our product candidates, if approved, our gross margins may decrease, which would adversely affect our ability to invest in and grow our business. To the extent any of our product candidates we develop are used in an outpatient setting, the commercial success of our product candidates will depend substantially, both domestically and abroad, on the extent to which coverage and reimbursement for these products and related treatments are available from government health programs and third- party payors. If coverage is not available, or reimbursement is limited, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investments. Government authorities and third- party payors, such as health insurers and managed care organizations, publish formularies that identify the medications they will cover and the related payment levels. The healthcare industry is focused on cost containment, both in the United States and elsewhere. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. Increasingly, third- party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for outpatient drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government- funded and private payors for any approved products used on an outpatient basis that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. We cannot predict whether bacteria may develop resistance to our product candidates, if approved, which could affect their revenue potential. Certain of our product candidates are designed to treat bacterial infections, including drug- resistant infections. The bacteria responsible for these infections evolve quickly and readily transfer their resistance mechanisms within and between species. We cannot predict whether or when bacterial resistance to any of such product candidates may develop. For example, as a carbapenem, tebipenem HBr is not active against organisms expressing a resistance mechanism mediated by enzymes known as carbapenemases. Although occurrence of this resistance mechanism is currently rare, we cannot predict whether carbapenemase- mediated resistance will become widespread in regions where ~~we~~ tebipenem HBr may be marketed if it is approved. The growth of drug resistant infections in community settings or in countries with poor public health infrastructures, or the potential use of any of our product candidates outside of controlled hospital settings, could contribute to the rise of resistance. If resistance to any of our product candidates becomes prevalent, our ability to generate revenue from such product candidates could suffer. If we are not successful in discovering, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired. Although a substantial amount of our efforts will focus on our ongoing and planned clinical trials and potential approval of our product ~~candidates~~ **candidate** ~~, SPR720~~, tebipenem HBr **, as well as exploring clinical** and **development pathways forward for** ~~SPR206~~ **SPR720**, a key element of our strategy is to discover, develop and commercialize a portfolio of therapeutics to treat drug resistant bacterial infections. We are ~~seeking to do so through our internal research programs and are~~ exploring, and intend to explore in the future, strategic partnerships for the development of new product candidates. Research programs to identify product candidates **, whether pursued internally or through strategic partnerships,** require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following: • the research methodology used may not be successful in identifying potential product candidates; • we may be unable to successfully modify candidate compounds to be active in Gram- negative bacteria or defeat bacterial resistance mechanisms or identify viable product candidates in our screening campaigns; • competitors may develop alternatives that render our product candidates obsolete; • product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights; • a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; • a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; • a product candidate may not be accepted as safe and effective by patients, the medical community or third- party payors; and • the development of bacterial resistance to potential product candidates may render them ineffective against target infections. If we are unsuccessful in identifying and developing additional product candidates, our potential for growth may be impaired. Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of any products that we may develop. We face an inherent risk of product liability claims as a result of the clinical testing of our product candidates despite obtaining appropriate informed consents from our clinical trial participants. We will face an even greater risk if we obtain marketing approval for and commercially sell any of our product candidates. For example, we may be sued if any product that we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in: • reduced resources for our management to pursue our business strategy; • decreased demand for our product candidates or products that we may develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • initiation of

investigations by regulators; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • significant costs to defend resulting litigation; • substantial monetary awards to trial participants or patients; • loss of revenue; and • the inability to commercialize any products that we may develop. Although we maintain general liability insurance and clinical trial liability insurance, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if and when we receive marketing approval for and begin selling any of our product candidates. In addition, insurance coverage is becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could adversely affect our business, financial condition, results of operations and prospects. 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 wastes, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. We maintain workers' compensation insurance to cover us for costs and expenses that 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. Moreover, we do not currently 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, which could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions. Our internal computer systems, or those of our contract research organizations or other contractors or consultants, may fail or suffer cybersecurity incidents, which could result in a material disruption of our product development programs, and could subject us to liability. We utilize information technology systems and networks to process, transmit and store electronic information in connection with our business activities. As the use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. **In particular, ransomware attacks, including those from organized criminal threat actors, nation- states and nation- state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data, including sensitive customer information, loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the negative impact of a ransomware attack, it may be preferable to make payments to the threat actor (s), but we may be unwilling or unable to do so, including, for example, if applicable laws or regulations prohibit such payments. Finally, developments in artificial intelligence and machine learning provide threat actors with the capability to use more sophisticated means to attack our systems and may exacerbate cybersecurity risk.** These threats pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber- attacks or successfully mitigating their effects. Despite the implementation of security measures, our internal computer systems and those of our contract research organizations and other contractors and consultants are vulnerable to damage or disruption from hacking, computer viruses, malware, including ransomware, software bugs, unauthorized access, natural disasters, terrorism, war, and telecommunication, equipment and electrical failures. We have measures in place that are designed to prevent, and if necessary, to detect and respond to such cybersecurity incidents and breaches of privacy and security mandates. Our measures to prevent, respond to, and minimize such risks may be unsuccessful. While we have not, to our knowledge, experienced any significant system failure, accident or material cybersecurity incident to date, if such an event were to occur and cause interruptions in our operations or the operations of those third parties with which we contract, it could result in a material disruption of our programs and our business operations, as well as our financial condition. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Such a loss could also expose us to regulatory enforcement, civil liability and reputational damage. To the extent that any disruption or cybersecurity incident results in a loss of or damage to our data or applications, or inappropriate disclosure or theft of confidential or proprietary information, in addition to incurring liability, the further development of our product candidates could be delayed or our competitive position could be compromised. Additionally **,** such disruptions or cybersecurity incidents could result in enforcement actions by ~~United States~~ **U. S.** or foreign regulatory authorities, regulatory penalties, and other legal liabilities such as but not limited to private litigation, the incurrence of significant remediation costs, disruptions to our development programs, business operations and collaborations, diversion of management efforts and damage to our reputation, all of which could harm our business and operations. Our actual or perceived failure to comply with data protection laws and regulations could lead to government enforcement actions, private litigation and / or adverse publicity and could negatively affect our business. We are subject to domestic and international data protection laws and regulations that address privacy and data security and may affect our collection, use, storage, and transfer of personal information. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues with the potential to affect our business. In the United States, numerous federal and

state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health- related and other personal information. Failure to comply with data protection laws and regulations, where applicable, could result in government enforcement actions, which could include civil or criminal penalties, private litigation and / or adverse publicity and could negatively affect our operating results and business. For example, California has enacted the California Consumer Privacy Act (" CCPA "), which went into effect in January of 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, and **the federal** HIPAA protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. Additionally in 2020, California voters passed the California Privacy Rights Act (" CPRA "), which went into full effect on January 1, 2023. The CPRA significantly amends the CCPA, potentially resulting in further uncertainty, additional costs and expenses in an effort to comply and additional potential for harm and liability for failure to comply. Among other things, the CPRA established a new regulatory authority, the California Privacy Protection Agency, which is tasked with enacting new regulations under the CPRA and will have expanded enforcement authority. In addition to California, more U. S. states are enacting similar legislation, increasing compliance complexity and increasing risks of failures to comply. In 2023, comprehensive privacy laws in Virginia, Colorado, Connecticut, and Utah all took effect, and laws in Montana, Oregon, and Texas ~~will~~ **took effect in 2024. Laws in a number of other U. S. states took effect, or are set to** take effect **,** in ~~2024~~ **2025** ~~. In addition~~ , ~~laws~~ in **2026, and** ~~other U. S. states are set to take effect~~ beyond ~~2024~~ , and additional U. S. states have proposals under consideration, all of which are likely to increase our regulatory compliance costs and risks, exposure to regulatory enforcement action and other liabilities **. In addition, other federal and state laws establish additional requirements for protecting the privacy and security of health information that is not protected by HIPAA. For instance, Washington state recently passed the " My Health My Data " Act, which came into force in 2024 and regulates " consumer health data, " which is defined as " personal information that is linked or reasonably linkable to a consumer and that identifies a consumer' s past, present, or future physical or mental health. " The " My Health My Data " Act provides exemptions for personal data used or shared in connection with certain research activities, including data subject to 45 C. F. R. Parts 46, 50 and 56. Notably, the " My Health My Data " Act contains a private right of action. In addition, Nevada recently enacted a consumer health data privacy bill, SB 370, which also took effect in 2024, and regulates " consumer health data. " SB 370 shares many similarities with Washington' s " My Health My Data " Act, and Connecticut recently amended its comprehensive privacy law to include heighted regulation of " consumer health data. " Additional states may adopt health- specific privacy laws that could impact our business activities and our collection and handling of health- related data** . Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. For example, the European Parliament and the Council of the European Union adopted a comprehensive general data privacy framework called the General Data Protection Regulation (~~"~~ **"** GDPR ~~"~~ **"**), which took effect in May 2018 and governs the collection and use of personal data in the European Union, including by companies outside of the European Union. The GDPR, which is wide- ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third- party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, enhances enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to € 20 million or 4 % of the annual global revenues of the infringer, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR has been and will continue to be a rigorous and time- intensive process that has increased and will continue to increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we or our collaborators may be subject to fines and penalties, litigation and reputational harm in connection with any European activities, which could adversely affect our business, prospects, financial condition and results of operations. Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, we may find that we are violating the laws or regulations of another jurisdiction. Despite our efforts, we may not have fully complied in the past and may not in the future. That could require us to incur significant expenses, which could significantly affect our business. Failure to comply with data protection laws may expose us to risk of enforcement actions taken by data protection authorities or other regulatory agencies, private rights of action in some jurisdictions, and potential significant penalties if we are found to be non- compliant. Furthermore, the number of government investigations related to data security incidents and privacy violations continue to increase and government investigations typically require significant resources and generate negative publicity, which could harm our business and reputation. We or third parties upon whom we depend may be adversely affected by natural disasters and / or health epidemics, and our business, financial condition and results of operations could be adversely affected. Natural disasters could severely disrupt our operations and have a material adverse effect on our business operations. If a natural disaster, health epidemic or other events beyond our control occurred that prevented us from using all or a significant portion of our office, that damaged critical infrastructure, such as the manufacturing facilities of our third- party contract manufacturers, or that otherwise disrupted operations, it may be difficult for us to continue our business for a substantial period of time. Risks Related to Our Financial Position and Need for Additional Capital We have not generated any revenue from the sale of our products, have a history of losses and expect to incur substantial future losses; **The report of our auditor on our consolidated financial statements expresses substantial doubt**

about our ability to continue as a going concern; if we are unable to obtain additional capital, we may not be able to continue our operations on the scope or scale as currently conducted, and that could have a material adverse effect on our business, results of operations and financial condition. We have not generated any revenue from the sale of our products and have incurred losses in ~~each~~ **most** ~~year~~ **years** since our inception in 2013 ~~through 2022~~ . Our net ~~income~~ **loss** was $ ~~22~~ **68** . ~~8~~ **6** million during the year ended December 31, ~~2023~~ **2024** . All of our product candidates are in development, none have been approved for sale and we may never have a product candidate approved for commercialization. In accordance with **Accounting Standards Update (“** ASU **”)** 2014- 15, Disclosure of Uncertainties about an Entity’ s Ability to Continue as a Going Concern (Subtopic 205- 40), we **have** ~~are required to evaluate~~ **evaluated** whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern ~~from~~ **within one year after** the ~~issuance~~ date ~~of our~~ **that these consolidated** financial statements **are issued** . ~~We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least 12 months from the issuance of the financial statements included in this report~~ . Based on our cash and cash equivalents as of December 31, ~~2023~~ **2024 , together with earned and non-contingent development milestone payments from GSK, as well as other non- dilutive funding commitments** , we believe that our cash runway will be sufficient to fund ~~us~~ **our operating expenses and required capital expenditures** into ~~late~~ **the second quarter of** ~~2025~~ **2026 . During this period, we plan to prioritize advancing the Phase 3 clinical trial activities for tebipenem HBr under our GSK License Agreement and completing our analysis of the full dataset from the 25 treated patients in the Phase 2a proof- of- concept trial of SPR720** . Beyond this point we will need additional funding, which **we expect will** primarily consist of raising additional capital through some combination of equity or debt financings, potential new collaborations or ~~partnerships,~~ additional grant funding ~~and / or reducing cash expenditures~~ . If we are not able to secure adequate additional funding, we plan to make **further** reductions in spending. In that event, we may have to delay, scale back, or eliminate some or all of our planned **development** ~~clinical trials, research stage programs and commercial~~ activities **. The actions necessary to reduce spending under this plan at a level that mitigates the factors described above is not considered probable, as defined in the accounting standards and therefore, the full extent to which management may extend our funds through these actions may not be considered in management’ s assessment of our ability to continue as a going concern. As a result, management has concluded that substantial doubt exists about our ability to continue as a going concern** . We expect to continue to incur significant expenses and ~~increasing~~ operating losses for the foreseeable future; if we are unable to achieve commercialization, revenue from product sales, and, ultimately, profitability, the market value of our common stock will likely decline. We expect to continue to incur significant expenses and ~~increasing~~ operating losses for the foreseeable future as we continue to advance our product candidates through preclinical and clinical development and marketing approval for such candidates whose clinical trials are successful. Our expenses will also increase substantially if and as we: • conduct additional clinical trials and studies of our product candidates; • continue to discover and develop additional product candidates; • establish manufacturing and supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain marketing approval; • maintain, expand and protect our intellectual property portfolio; • hire additional clinical, scientific and commercial personnel; • add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, face competing technological and market developments; and • acquire or in- license other product candidates and technologies. **We currently have no products approved for sale and have historically invested a significant portion of our efforts and financial resources on the development of our product candidates, including tebipenem HBr, SPR206, and SPR720. Although we have decided to discontinue further development of SPR206 and are exploring strategic options, including potential out- licensing, to maximize the value for the program and allow us to leverage the expertise of strategic partners and have suspended our current development efforts with respect to the SPR720 oral program, although we continue to evaluate other potential paths forward as the remaining data are collected and analyzed, our business remains heavily dependent on the successful development, regulatory approval, and, if approved, commercialization of tebipenem HBr and other future product candidates. We cannot be certain that any product candidate will receive regulatory approval or will be successfully commercialized even if it receives regulatory approval.** If our product candidates fail to demonstrate safety and efficacy in clinical trials, do not gain regulatory approval, or do not achieve market acceptance following regulatory approval and commercialization, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders’ equity and working capital. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline. Because of the numerous risks and uncertainties associated with developing biopharmaceutical products, we are unable to predict the extent of any future losses or when, if ever, we will become profitable. Our expenses could increase if we are required by the FDA, or any comparable foreign regulatory authority to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates. We expect that we will need substantial additional funding. If we are unable to raise capital when needed, or do not receive ~~payment~~ **payments** under our government awards **or from our commercial partnership agreements** , we could be forced to delay, reduce or eliminate our product development programs. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time- consuming, expensive and uncertain process that takes years to complete. **Our** ~~We expect that our~~ expenses ~~will continue~~ **are likely** to increase as we commence and advance our ongoing and planned clinical trials and other studies ~~of~~ **for our current and future product candidates, as well as explore clinical and development pathways forward for** SPR720 ~~, tebipenem HBr and SPR206~~ . If we obtain marketing approval for any product candidate, we expect to incur significant expenses related to development, product sales, marketing, distribution and manufacturing. Some of these expenses may be incurred in advance of marketing approval ~~,~~ and could be substantial. Accordingly, we will be required to obtain further funding through public or

private equity offerings, debt financings, collaborations, licensing arrangements, government funding 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 effect on our financial condition and our ability to pursue our business strategy. ~~We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least 12 months from the issuance of the financial statements included in this report.~~ Based on our cash and cash equivalents as of December 31, ~~2023~~ **2024 , together with earned and non- contingent development milestone payments from GSK, as well as other non- dilutive funding commitments** , we believe that our cash runway will be sufficient to fund ~~us~~ **our operating expenses and capital expenditures** into ~~late~~ **the second quarter of** ~~2025~~ **2026** . ~~Our cash forecasts~~ **During this period, we plan to prioritize advancing the Phase 3 clinical trial activities for tebipenem HBr under our GSK License Agreement and completing our analysis of the full dataset from the 25 treated patients in the Phase 2a proof- of- concept trial of SPR720. Beyond this point we will need additional funding, which we expect will primarily consist of raising additional capital through some combination of equity or debt financings, potential new collaborations or additional grant funding. If we** are ~~based on assumptions~~ **not able to secure adequate additional funding, we plan to make further reductions in spending. In** that **event** ~~may prove to be wrong~~ , ~~and~~ we ~~could use our available capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Our future funding requirements, both short- term and long- term, will depend on many~~ - **may** ~~factors~~ **have to delay, scale back, or eliminate some or all of our planned development activities** , including: • the timing and terms of the potential FDA approval of tebipenem HBr; • the timing, costs and results of our ongoing, planned and potential clinical trials for our product candidates; • the amount of funding that we receive under our government awards; • the number and characteristics of product candidates that we pursue; • the outcome, timing and costs of seeking regulatory approvals; • the costs of commercialization activities for our product candidates if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities; • the terms and timing of any future collaborations, licensing or other arrangements that we may establish; • the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreements; • the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property related claims; • the costs of our continued operation as a public company; and • the extent to which we in- license or acquire other products and technologies. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, collaborations, licensing arrangements and government funding arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. We filed a universal shelf registration statement on Form S- 3 (Registration No. 333- 254170) with the SEC on March 11, 2021, which was declared effective on March 29, 2021 **(the " 2021 Form S- 3 ")** , and pursuant to which we registered for sale up to $ 300. 0 million of any combination of our common stock, preferred stock, debt securities, warrants, rights and / or units from time to time and at prices and on terms that we ~~may~~ **could** determine, including up to $ 75. 0 million of our common stock available for issuance pursuant to the Controlled Equity Offering Sales Agreement (**the** " Sales Agreement ") that we entered into with Cantor Fitzgerald & Co. (" Cantor "). The 2021 Form S- 3 ~~will expire~~ **expired** on March 29, 2024 **. We filed a new universal shelf registration statement on Form S- 3 (Registration No. 333- 277998) with the SEC on March 15, 2024, which became effective on March 22, 2024 and pursuant to which we registered for sale up to $ 300. 0 million of any combination of our common stock, preferred stock, debt securities, warrants, rights and / or units from time to time and at prices and on terms that we may determine, including up to $ 75. 0 million of our common stock available for issuance pursuant to the Sales Agreement with Cantor** . Under the Sales Agreement, Cantor may sell shares of our common stock by any method permitted by law deemed to be an " at - the - market " offering as defined in Rule 415 of the Securities Act **of 1933, as amended (the " Securities Act ")** , subject to the terms of the Sales Agreement **. While we currently have an effective shelf registration statement, as of the filing of this Annual Report on Form 10- K, our public float is less than $ 75 million, and under SEC regulations for so long as our public float remains less than $ 75 million, the amount we can raise through primary public offerings of securities in any twelve- month period using shelf registration statements is limited to an aggregate of one- third of our public float, which is referred to as the baby shelf rules. As of March 21, 2025, our public float was approximately $ 45. 1 million, based on 54, 969, 832 shares of outstanding common stock held by non- affiliates and at a price of $ 0. 82 per share, which was the closing price of our common stock on the Nasdaq Global Select Market (" Nasdaq GS ") on March 21, 2025. As a result of our public float being below $ 75 million, we will be limited by the baby shelf rules until such time our public float exceeds $ 75 million, which means we only have the capacity to sell shares up to one- third of our public float in primary offerings under our shelf registration statement on Form S- 3 in any twelve- month period. Although alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms** . We may seek to raise additional capital at any time. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interest of our then existing stockholders may be materially 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, debt financing, if available, would result in increased 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 or declaring dividends, which could adversely affect our ability to conduct our business. In addition, securing additional financing would 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 development of our product candidates. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. Our ability to use our net operating loss carryforwards may be limited. As of December 31, ~~2023~~ **2024** , we had ~~United States~~ **U. S.** federal, state and foreign net operating loss carryforwards (~~"~~ **"** NOLs ~~"~~ **"**) of $ ~~94~~ **165** . ~~7~~ **2** million, $ ~~90~~ **120** . ~~9~~ **6** million and $ 4. 6 million, respectively. ~~All~~ **$ 152. 0 million of the** ~~Federal~~ **federal** NOLs can be carried forward indefinitely **and $ 13. 2 million of the federal NOLs begin to expire in 2034** . The state NOLs begin to expire in ~~2033~~ **2034** and will expire at various dates through ~~2043~~ **2044** . The foreign NOLs do not expire. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. ~~These state~~ **Aside from the NOLs that can be carried forward indefinitely, the remaining** NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended (the" Code") and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 % change, by value, in its equity ownership by 5 % stockholders over a three- year period, the corporation' s ability to use its pre- change NOLs and other pre- change tax attributes to offset its post- change income may be limited. We recently completed a Section 382 study and concluded that we underwent several ownership changes as defined by the Code, the last of which occurred during the year ended December 31, 2018. Any carryforwards that will expire prior to utilization were removed from deferred tax assets, with a corresponding reduction of the valuation allowance. Future ownership changes may limit our ability to utilize remaining tax attributes. Under current ~~United States~~ **U. S.** federal tax legislation, although the treatment of NOLs arising in tax years beginning on or before December 31, 2017 has generally not changed, NOLs arising in tax years beginning after December 31, 2017 may be used to offset only 80 % of taxable income. In addition, net operating losses arising in tax years beginning after December 31, 2017 may be carried forward indefinitely, as opposed to the 20- year carryforward under prior law. 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 were established in 2013 and began operations in 2014.~~ Our operations to date have been limited to financing and staffing our company, **and performing research and** ~~developing~~ **development** ~~our technology and~~ **activities to advance** our product candidates **. Each of our product candidates is either in clinical or preclinical development** . We have not yet demonstrated an ability to successfully obtain marketing approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, 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 developing and commercializing pharmaceutical products. We ~~may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We have begun 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. 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. Accordingly, stockholders should not rely upon the results of any quarterly or annual periods as indications of future operating performance ~~. We and certain of our current and former executive officers have been named as defendants in two initiated lawsuits, which were ordered consolidated, that could result in substantial costs and divert management' s attention. We, and certain of our executive officers, were named as defendants in two purported class action lawsuits that generally allege that we and certain of our current and former officers violated Sections 10 (b) and / or 20 (a) of the Securities Exchange Act of 1934 and Rule 10b- 5 promulgated thereunder by making allegedly false and / or misleading statements concerning the NDA for tebipenem HBr in an effort to lead investors to believe that the drug would receive approval from the FDA. The parties moved to consolidate the two complaints on July 22, 2022, which were ordered consolidated on August 5, 2022. The parties filed an Amended Complaint on December 5, 2022, purported to be brought on behalf of stockholders who purchased our common stock from September 8, 2020 through May 2, 2022. The Amended Complaint generally alleges that we and certain of our current and former officers violated Sections 10 (b) and / or 20 (a) of the Exchange Act and Rule 10b- 5 promulgated thereunder by making allegedly false and / or misleading statements concerning the NDA for tebipenem HBr in an effort to lead investors to believe that the drug would receive approval from the FDA. Plaintiffs seek unspecified damages, interest, attorneys' fees, and other costs. We filed a fully- briefed Motion to Dismiss on June 21, 2023. The Court has not yet ruled on the Motion. We intend to engage in a vigorous defense of the lawsuit. However, we are unable to predict the outcome of this matter at this time. Moreover, any conclusion of this matter in a manner adverse to us would have a material adverse effect on our financial condition and business. We could incur substantial costs not covered by our directors' and officers' liability insurance, suffer a significant adverse impact on our reputation and divert management' s attention and resources from other priorities, including the execution of business plans and strategies that are important to our ability to grow our business, any of which could have a material adverse effect on our business. In addition, this matter could require payments that are not covered by, or exceed the limits of, our available directors' and officers' liability insurance, which could have a material adverse effect on our operating results or financial condition~~ . Risks Related to Our Dependence on Third Parties We may not achieve the milestones triggering payments to us in our license and collaboration agreements with third parties. We have and may continue to seek third- party collaborators for development and commercialization of certain of our product candidates. Currently we are party to license and collaboration agreements with third parties as described in Note ~~14~~ **13** (" License, Collaboration and Service Agreements ") to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10- K. Our likely collaborators for any other marketing, distribution,

development, licensing or broader collaboration arrangements we may pursue include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We may derive revenue from research and development fees, license fees, milestone payments and royalties under any collaborative arrangement into which we enter. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, our collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. As a result, we can expect to relinquish some or all of the control over the future success of a product candidate that we license to a third party. We face significant competition in seeking and obtaining appropriate collaborators. Collaborations involving our product candidates may pose a number of risks, including the following: • collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations; • collaborators may not perform their obligations as expected; • collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities; • collaborators may not be able to develop, manufacture, market and sell our product candidates and use our intellectual property without infringing or misappropriating the intellectual property and other proprietary rights of third parties; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; • product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates; • a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products; • disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; • collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and • collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a collaborator of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us. We may have to alter our development and commercialization plans if we are not able to establish collaborations. We will require additional funds to complete the development and potential commercialization of our product candidates. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. Moreover, we intend to utilize a variety of types of collaboration arrangements for the potential commercialization of our product candidates outside the United States. 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 design or results of clinical trials; • the likelihood of approval by the FDA or comparable foreign regulatory authorities; • the potential market for the subject product candidate; • the costs and complexities of manufacturing and delivering such product candidate to patients; • the potential for competing products; • our patent position protecting the product candidate, including any uncertainty with respect to our ownership of our technology or our licensor' s ownership of technology we license from them, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; • the need to seek licenses or sub- licenses to third- party intellectual property; and • industry and market conditions generally. 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. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, 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. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and our business may be materially and adversely affected. We rely on third parties to conduct all of our nonclinical studies and all of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize any of our product candidates. If they do not perform satisfactorily, our business may be materially harmed. We do not independently conduct nonclinical studies that comply with GLP requirements. We also do not have the ability to independently conduct clinical trials of any of our product candidates. We rely on third parties, such as contract research organizations, clinical

data management organizations, medical institutions and clinical investigators, to conduct our clinical trials of our product candidates and potential product candidates. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities and increase our costs. Our reliance on these third parties for clinical development activities limits our control over these activities but we remain responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. For example, notwithstanding the obligations of a contract research organization 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 and applicable regulatory requirements. While we will have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP studies and our clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. Although we rely on these third parties to conduct our GLP- compliant nonclinical studies and clinical trials, we remain responsible for ensuring that each of our nonclinical studies and clinical trials are conducted in accordance with applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. The FDA and regulatory authorities in other jurisdictions also require us to comply with standards, commonly referred to as **GCPs** ~~good clinical practices~~ for conducting, monitoring, recording and reporting the results of clinical trials to assure that data and reported results are accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and institutional review boards. If we or our third- party contractors fail to comply with applicable GCP standards, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot make assurances that, upon inspection, the FDA will determine that any of our clinical trials comply with GCP. 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 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 may 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 our product candidates could be harmed, our costs could increase and our ability to generate revenue could be delayed, impaired or foreclosed. We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue. We contract with third parties for the manufacture of preclinical and clinical supplies of our product candidates and expect to continue to do so in connection with any future commercialization and for any future clinical trials and commercialization of our other product candidates and potential product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. We do not currently have nor do we plan to build the internal infrastructure or capability to manufacture our product candidates for use in the conduct of our preclinical research, our clinical trials or for commercial supply. We currently rely on and expect to continue to rely on third- party contract manufacturers to manufacture supplies of our product candidates, and we expect to rely on third- party contract manufacturers to manufacture commercial quantities of any product candidate that we commercialize following approval for marketing by applicable regulatory authorities, if any. Reliance on third- party manufacturers entails risks, including: • manufacturing delays if our third- party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us; • the possible termination or nonrenewal of the agreement by the third- party at a time that is costly or inconvenient for us; • the possible breach of the manufacturing agreement by the third- party; • the failure of the third- party manufacturer to comply with applicable regulatory requirements; and • the possible misappropriation of our proprietary information, including our trade secrets and know- how. We currently rely on a small number of third- party contract manufacturers and one supplier for all of our required raw materials, drug substance and finished product for our preclinical research and clinical trials. We do not have long- term agreements with any of these third parties. We also do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates. If any of our existing manufacturers should become unavailable to us for any reason, we may incur delays in identifying or qualifying replacements. In addition, because some of our manufacturers have manufacturing facilities in Taiwan, their ability to provide us with adequate supplies of high- quality products on a timely and cost- efficient basis is subject to a number of additional risks and uncertainties, including political, social and economic instability and factors that could impact the shipment of supplies. If our manufacturers are unable to provide us with adequate supplies of high- quality products on a timely and cost- efficient basis, our operations would be disrupted and our net revenue and profitability would suffer. Our third- party contract manufacturers are based in Asia. Recently, our third- party contract manufacturers have been subject to various supply chain disruptions. These supply chain disruptions have increased the price of certain materials due to the significant increase in costs of raw materials and shipping costs. Our ability to produce and timely deliver our products may be materially

impacted in the future if these supply chain disruptions continue or worsen. Further, a major catastrophe, such as an earthquake or other natural disaster, labor strike, or work stoppage at any of our manufacturing facilities, or a manufacturing facility of our suppliers or customers, could result in a prolonged interruption of our business. A disruption resulting from any one of these events could cause significant delays in shipments of our products and the loss of revenue and customers, which could have a material adverse effect on our financial position, results of operations, and cash flows. Our facilities in Japan and Taiwan are located in seismically- active areas. If any of our product candidates are approved by any regulatory agency, we intend to enter into agreements with third- party contract manufacturers for the commercial production of those products. This process is difficult and time consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third- party manufacturers on satisfactory terms, which could delay our commercialization. Third- party manufacturers are required to comply with cGMPs and similar regulatory requirements outside the United States. Facilities used by our third- party manufacturers must be approved by the FDA after we submit an NDA and before potential approval of the product candidate. Similar regulations apply to manufacturers of our product candidates for use or sale in foreign countries. We do not control the manufacturing process and are completely dependent on our third- party manufacturers for compliance with the applicable regulatory requirements for the manufacture of our product candidates. The inability or failure of our manufacturers to successfully manufacture material that conforms to the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, may require us to find alternative manufacturing facilities, which could result in delays in obtaining approval for the applicable product candidate. In addition, our manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMPs or other regulatory requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and have a material adverse effect on our business, financial condition and results of operations. Our current and anticipated future dependence upon others for the manufacture of our product candidates and potential product candidates may adversely affect our future profit margins and our ability to commercialize any products for which we receive marketing approval on a timely and competitive basis. If we fail to comply with our obligations in the agreements under which we in- license or **out- license** acquire development or commercialization rights to products, technology or data from **or to** third parties, we could lose such rights that are important to our business. We are a party to agreements with Meiji and GSK for tebipenem HBr, Vertex Pharmaceuticals for SPR720 and Pfizer, Everest and PBB Distributions Limited for SPR206, and we may enter into additional agreements, including license agreements, with other parties in the future that impose diligence, development and commercialization timelines, milestone payments, royalties, insurance and other obligations on us. For example, we have the Meiji License that gives us rights outside of the Meiji Territory to develop, manufacture, and commercialize tebipenem HBr as well as the right to use, cross- reference, file or incorporate by reference any information and relevant Meiji regulatory documentation to support any regulatory filings outside of the Meiji Territory. In addition, we have the right to develop, manufacture and have manufactured tebipenem HBr in the Meiji Territory solely for the purpose of furthering development, manufacturing and commercialization of tebipenem HBr outside of the Meiji Territory. In exchange for those rights, we are obligated to satisfy diligence requirements, including using commercially reasonable efforts to develop and commercialize tebipenem HBr and to implement a specified development plan, meeting specified development milestones and providing an update on progress on an annual basis. The Meiji License requires us to pay future milestone payments of up to $ 1. 0 million upon the achievement of specified regulatory milestones and royalties of a low single- digit percentage on net sales on a country- by- country basis. In addition, pursuant to our GSK License Agreement, we granted GSK an exclusive royalty- bearing license, with the right to grant sublicenses, under our intellectual property and regulatory documents and a sublicense under certain intellectual property of Meiji and Meiji' s regulatory documents to develop, manufacture and commercialize the GSK Licensed Products in the GSK Territory. Under the terms of the GSK License Agreement, we received an upfront payment of $ 66. 0 million for GSK to secure rights to the medicine, a $ 30. 0 million milestone payment upon achievement of a development milestone in the third quarter of 2023, and are entitled to receive a $ 95. 0 million development milestone that is payable in four equal semi- annual installments **, of which we received $ 23. 8 million in February 2024, $ 23. 8 million in August 2024 and $ 23. 8 million in February 2025** . Remaining potential payments **under the GSK License Agreement** are milestone based and are (i) approximately $ 25. 0 million in payments for ~~the achievement~~ **GSK' s submission** of ~~development milestones~~ **a NDA with the FDA for tebipenem HBr** , (ii) up to $ 150. 0 million in commercial milestone payments, (iii) up to $ 225. 0 million in sales milestone payments, and (iv) tiered low single- digit to low double- digit royalties (if sales exceed $ 1. 0 billion) tiered on net sales of GSK Licensed Products in the GSK Territory. We are responsible for the execution and costs of the follow- up Phase 3 clinical trial of tebipenem HBr. GSK is responsible for the execution and costs of additional further development, including Phase 3 regulatory filing and commercialization activities for tebipenem HBr in the balance of the GSK Territory outside of the United States. We will also be responsible for providing and paying for the clinical supply of tebipenem HBr while GSK will be responsible for the costs of the commercial supply of tebipenem HBr. If we fail to comply with our obligations to Meiji, GSK, or any of our other partners, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product candidate that is covered by these agreements, which could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Risks Related to Our ~~United States~~ **U. S.** Government Contracts and to Certain Grant Agreements Our use of

government funding for certain of our programs adds complexity to our research and commercialization efforts with respect to those programs and may impose requirements that increase the costs of commercialization and production of product candidates developed under those government- funded programs. We have received significant non- dilutive financing from various government agencies for the further development of our product candidates. Such funding sources may pose risks to us not encountered in other commercial contracts, including significant regulatory compliance risks. Contracts funded by the United States government and its agencies include provisions that reflect the government' s substantial public policy and compliance requirements, and substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to: • terminate agreements, in whole or in part, for any reason or no reason; • reduce or modify the government' s obligations under such agreements without the consent of the contractor; • claim rights, including intellectual property rights, in products and data developed under such agreements; • audit contract- related costs and fees, including allocated indirect costs; • suspend the contractor from receiving new contracts pending resolution of alleged violations of procurement laws or regulations; • impose ~~United States~~ **U. S.** manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements; • suspend or debar the contractor or grantee from doing future business with the government; • control and potentially prohibit the export of products; and • pursue criminal or civil remedies under the False Claims Act (the ~~"~~ **“** FCA ~~"~~ **”**), the False Statements Act and similar remedy provisions specific to government agreements. We may not have the right to prohibit the ~~United States~~ **U. S.** government from using certain technologies developed by us, and we may not be able to prohibit third- party companies, including our competitors, from using those technologies in providing products and services to the ~~United States~~ **U. S.** government. The ~~United States~~ **U. S.** government generally takes the position that it has the right to royalty- free use of technologies that are developed under ~~United States~~ **U. S.** government contracts. In addition, government contracts and grants, and subcontracts and subawards awarded in the performance of those contracts and grants, normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example: • specialized accounting systems unique to government awards; • mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent; • public disclosures of certain award information, which may enable competitors to gain insights into our research program; and • mandatory socioeconomic compliance requirements, including labor standards, anti- human- trafficking, non- discrimination and affirmative action programs, energy efficiency and environmental compliance requirements. If we fail to maintain compliance with these requirements, we may be subject to potential contract or FCA liability and to termination of our contracts. ~~United States~~ **U. S.** government agencies have special contracting requirements that give them the ability to unilaterally control our contracts. ~~United States~~ **U. S.** government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. These risks include the ability of the ~~United States~~ **U. S.** government to unilaterally: • audit and object to our government contract- related costs and fees, and require us to reimburse all such costs and fees; • suspend or prevent us for a set period of time from receiving new contracts or extending our existing contracts based on violations or suspected violations of laws or regulations; • cancel, terminate or suspend our contracts based on violations or suspected violations of laws or regulations; • terminate our contracts if in the government' s interest, including if funds become unavailable to the applicable governmental agency; • reduce the scope and value of our contract; and • change certain terms and conditions in our contract. The ~~United States~~ **U. S.** government will be able to terminate any of its contracts with us, either for convenience or if we default by failing to perform in accordance with or to achieve the milestones set forth in the contract schedules and terms. Termination- for- convenience provisions generally enable us to recover only our costs incurred or committed and settlement expenses on the work completed prior to termination. Except for the amount of services received by the government, termination- for- default provisions do not permit these recoveries and would make us liable for excess costs incurred by the United States government in procuring undelivered items from another source. Our business is subject to audit by the ~~United States~~ **U. S.** government and other potential sources for grant funding, including under our contracts with BARDA ~~,~~ **and** NIAID ~~and DoD,~~ and a negative outcome in an audit could adversely affect our business. United States government agencies such as the DHHS and the Defense Contract Audit Agency (the ~~"~~ **“** DCAA ~~"~~ **”**) routinely audit and investigate government contractors. These agencies review a contractor' s performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. The DHHS and the DCAA also review the adequacy of, and a contractor' s compliance with, its internal control systems and policies, including the contractor' s purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be paid, while such costs already paid must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including: • termination of contracts; • forfeiture of profits; • suspension of payments; • fines; and • suspension or prohibition from conducting business with the United States government. In addition, we could suffer serious reputational harm if allegations of impropriety were made against us, which could cause our stock price to decrease. Laws and regulations affecting government contracts make it more expensive and difficult for us to successfully conduct our business. We must comply with numerous laws and regulations relating to the formation, administration and performance of government contracts, which can make it more difficult for us to retain our rights under our government contracts. These laws and regulations affect how we conduct business with government agencies. Among the most significant government contracting regulations that affect our business are: • the Federal Acquisition Regulations (the ~~"~~ **“** FAR ~~"~~ **”**) and agency- specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts; • business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and include other requirements such as the Anti- Kickback Statute and the Foreign Corrupt Practices Act; • export and import control laws and regulations; and • laws, regulations and executive orders restricting the use

and dissemination of information classified for national security purposes and the exportation of certain products and technical data. These requirements change frequently, such as through appropriations bills or executive orders. Any changes in applicable laws and regulations could restrict our ability to maintain our existing BARDA and other government contracts and obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our results of operations. Provisions in our ~~United States~~ **U. S.** government contracts, including our contracts with BARDA, may affect our intellectual property rights. Certain of our activities have been funded, and may in the future be funded, by the ~~United States~~ **U. S.** government, including through our contracts with BARDA. When new technologies are developed with ~~United States~~ **U. S.** government funding, the government obtains certain rights in any resulting patents, including the right to a nonexclusive license authorizing the government to use the invention and rights that may permit the government to disclose our confidential information to third parties and to exercise " march- in " rights. The government can exercise its march- in rights if it determines that action is necessary because we fail to achieve practical application of the ~~United States~~ **U. S.** government- funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to ~~United States~~ **U. S.** industry. In addition, ~~United States~~ **U. S.** government- funded inventions must be reported to the government, ~~United States~~ **U. S.** government funding must be disclosed in any resulting patent applications, and our rights in such inventions may be subject to certain requirements to manufacture products in the United States. Risks Related to Our Intellectual Property If we are unable to obtain and maintain sufficient patent protection for our technology or our product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be adversely affected. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary chemistry technology and product candidates. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage that 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 technologies and product candidates that are important to our business. 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. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. 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 technologies commonly involves complex legal and factual questions, which has 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. Furthermore, changes in patent laws in the United States, including those made by the America Invents Act of 2011, may affect the scope, strength and enforceability of our patent rights or the nature of proceedings which may be brought by us related to our patent rights. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and 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. 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, in the ~~US~~ **United States,** there is an exception for one' s own publication of an invention prior to filing a patent application for the invention. Most other countries have no such exception and any publication prior to filing is an absolute bar to patentability. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of the America Invents Act of 2011, the United States transitioned to a first- inventor- to- file system in March 2013, under which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent. However, as a result of the lag in the publication of patent applications following filing in the United States, we are still not be able to be certain upon filing that we are the first to file for patent protection for any invention. Moreover, we may be subject to a third- party **pre-** ~~preissuance~~ --- **issuance** submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. Due to the war in Ukraine and sanctions between the United States and Russia, patents and patent applications in Russia, the EAPO and Ukraine currently have an uncertain fate. Unless the conflict with Ukraine ends quickly it is unlikely our Russian and EAPO patent and patent applications will remain in effect. Ukraine is currently under martial law and not processing patent applications. It is expected all patent deadlines in Ukraine will be extended. Even if our patent applications issue as patents, they may not issue in a form that will 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 owned or licensed patents by developing similar or alternative technologies or products in a non- infringing manner. 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 and / or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and / or assert our

patents, 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 and / or unenforceable. 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. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, 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 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, or those of our licensors. 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, in a 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 patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our 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. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. 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. 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. If we are sued for infringing intellectual property rights of third parties, or otherwise become involved in disputes regarding our intellectual property rights, 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 and use our proprietary chemistry technology without infringing the intellectual property and other proprietary rights of third parties. Numerous third-party ~~United States~~ **U. S.** and non- ~~United States~~ **U. S.** issued patents and pending applications exist in the area of antibacterial treatment, including compounds, formulations, treatment methods and synthetic processes that may be applied towards the synthesis of antibiotics. If any of their patents or patent applications cover our product candidates or technologies, we may not be free to manufacture or market our product candidates as planned. 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 technology or product candidates, including interference proceedings before the USPTO. Intellectual property disputes arise in a number of areas including with respect to patents, use of other proprietary rights and the contractual terms of license arrangements. Third parties may assert claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. With respect to our Meiji License of certain know- how and regulatory documents concerning tebipenem pivoxil, we are neither a party to, nor an express third- party beneficiary of, the letter agreements, which were signed in January 2017 and in February 2022, between Meiji and Global Pharma consenting to Meiji' s arrangements with us. As such, if any dispute among the parties were to occur, our direct enforcement rights with respect to the letter agreements may be limited or uncertain. If we are found to infringe a third party' s intellectual property rights, we or our third **-** party collaborators could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we or they 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 candidate. However, we or such collaborators 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. 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 product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we or our third **-** party collaborators have misappropriated the intellectual property, confidential information or trade secrets of third parties could have a similar negative effect on our business. We may be subject to claims that we or our employees, consultants or contractors have misappropriated the intellectual property of a third party, or claims asserting ownership of what we regard as our own intellectual property. Many of our employees, consultants and contractors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that these individuals do not use the intellectual property and

other proprietary information or know- how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed such intellectual property or other proprietary information. Litigation may be necessary to defend against these claims. 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. To the extent that we fail to obtain such assignments or such assignments are breached, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our 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 or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel. If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed. In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, in seeking to develop and maintain a competitive position. 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 consultants, independent contractors, advisors, corporate collaborators, outside scientific collaborators, contract manufacturers, suppliers and other third parties. We, as well as our licensors, also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. 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. In addition, 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. We have registered trademarks and pending trademark applications. Failure to enforce our registered marks or secure registration of our pending trademark applications could adversely affect our business. We have registered our trademarks for our name and logo in the United States and other countries and have a number of pending trademark applications in the United States and other countries. As of December 31, ~~2023~~ **2024** , we have two registered ~~United States~~ **U. S.** trademarks, 23 registered foreign trademarks, and no pending foreign trademark applications. If our registered trademarks are invalidated, we may be unable to exclusively use our name or logo in certain jurisdictions or may need to change our name or logo in certain jurisdictions, which could affect our business. If we do not secure registrations for our pending trademark applications, we may encounter more difficulty in enforcing them against third parties, which could adversely affect our business. We have applied to register our product candidate name as a trademark in the United States, where it has been allowed for registration, and have applied to register the mark in three foreign jurisdictions. We have also applied to register additional product candidate names as trademarks in the United States. When we file trademark applications for our product candidates, those applications may not be allowed for registration, and registered trademarks may not be obtained, maintained, or enforced. During trademark registration proceedings in the United States and foreign jurisdictions, we may receive rejections. We are given an opportunity to respond to those rejections, but we may not be able to overcome such rejections. In addition, in the **USPTO** ~~United States Patent and Trademark Office~~ and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In addition, any proprietary name we propose to use with any product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Risks Related to Regulatory Approval and Other Legal Compliance Matters If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired. Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities, with regulations differing from country to country. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and have relied on third- party contract research organizations to assist us in this process. The time required to obtain approval, if any, by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our product candidates we seek to develop in the future will ever obtain regulatory approval. Neither we nor any future collaborators are permitted to market any of our product candidates in the United States until we or they receive regulatory approval of an NDA from the FDA. In order to obtain approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate to the satisfaction of the FDA or

foreign regulatory agencies, 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 that the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for our product candidates either prior to or post- approval, and it may otherwise object to elements of our clinical development program. An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate' s safety and efficacy for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product candidate. Foreign regulatory authorities have differing requirements for approval of drugs with which we must comply with prior to marketing. Obtaining marketing approval for marketing of a product candidate in one country does not ensure that we will be able to obtain marketing approval in other countries, but the failure to obtain marketing approval in one jurisdiction could negatively affect our ability to obtain marketing approval in other jurisdictions. The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for many reasons, including: • the FDA or the applicable foreign regulatory agency' s disagreement with the design or implementation of our clinical trials; • negative or ambiguous results from our clinical trials or results that 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 experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates; • our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that our product candidates are safe and effective for the proposed indication; • the FDA' s or the applicable foreign regulatory agency' s disagreement with the interpretation of data from nonclinical studies or clinical trials; • our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks; • the FDA' s or the applicable foreign regulatory agency' s requirement for additional nonclinical studies or clinical trials; • the FDA' s or the applicable foreign regulatory agency' s disagreement regarding the formulation, labeling and / or the specifications for our product candidates; or • the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval. Of the large number of drugs in development, only a small percentage complete the FDA or foreign regulatory approval processes and are successfully commercialized. The lengthy review process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval, which would significantly harm our business, financial condition, results of operations and prospects. Even if we eventually receive approval of an NDA or foreign marketing application for our product candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials, often referred to as Phase 4 clinical trials, and the FDA may require the implementation of a REMS which may be required to ensure safe use of the drug after approval. The FDA or the applicable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. 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. A fast track designation may not actually lead to a faster development or regulatory review or approval process. We have received fast track designation for tebipenem HBr for the treatment of cUTIs, including pyelonephritis, in adult patients who have limited oral treatment options, as well as fast track designation for SPR720 for treatment of adult patients with NTM pulmonary disease, and we may seek fast track designation for one or more of our other product candidates in the future. If a drug is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a drug sponsor may apply for fast track designation by the FDA for the particular indication under study. If fast track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This " rolling review " is available if the applicant provides and the FDA approves a schedule for the remaining information. If we seek fast track designation for a product candidate, we may not receive it from the FDA. However, even if we receive fast track designation, fast track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with fast track designation compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA' s priority review procedures. Priority review designation by the FDA may not lead to a faster regulatory review or approval process and, in any event, does not assure FDA approval. If the FDA determines that a product candidate intended to treat a serious disease, if approved, would provide a significant improvement in safety or effectiveness of the treatment of the disease, the FDA may designate the drug application for that product candidate for priority review. A priority review designation means that the goal for the FDA to review the marketing application is six months from the date of NDA acceptance for filing, rather than the standard review period of ten months from the date of NDA acceptance for filing. A priority review designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving a priority review designation from the FDA does not guarantee approval of the drug application within the six- month review cycle or any time thereafter. While we have negotiated a SPA agreement with the FDA relating to our pivotal Phase 3 clinical trial of tebipenem HBr in patients with cUTI, including AP, this agreement does not guarantee approval of tebipenem HBr or any other particular outcome from regulatory review of the clinical trial or the product candidate. On July 31, 2023, the Company announced that it received written agreement from the FDA, under a SPA, on the design and size of PIVOT- PO, a pivotal Phase 3 clinical trial of tebipenem HBr in patients with cUTI, including AP. The FDA' s SPA process is designed to allow the FDA to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for

determining a drug product' s efficacy, among other eligible protocols. Upon specific written request by a clinical trial sponsor, the FDA will evaluate the planned protocol and respond to a sponsor' s questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis. The FDA ultimately assesses whether the protocol design and planned analysis of the trial adequately address scientific and regulatory requirements for the particular purposes identified by the sponsor, which in this case was that the PIVOT- PO protocol can be considered an adequate and well- controlled study in support of our future resubmission of the tebipenem HBr marketing application. All agreements between the FDA and the sponsor regarding an SPA must be clearly documented in writing, either in the form of an SPA letter or minutes of a meeting between the sponsor and the FDA at which the SPA agreement was reached. However, an SPA agreement does not guarantee approval of a product candidate, and even if the FDA agrees to the design, execution and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, if other new scientific concerns regarding product safety or efficacy arise, if the sponsor fails to comply with the agreed upon trial protocols or modifies such protocols without prior FDA agreement, or if the relevant data, assumptions or information provided by the sponsor change or are found to be false or omit relevant facts. In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, so long as the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of an SPA agreement, as well as the data and results obtained from any study that is the subject of the SPA agreement. We cannot assure you that our pivotal Phase 3 clinical trial will succeed, or that the SPA agreement will ultimately be binding on the FDA or will result in any FDA approval of tebipenem HBr. We expect that the FDA will review our compliance with the protocol that is subject to the SPA agreement, and, as with all NDA reviews, evaluate the results of the trial and conduct inspections of some of the sites where the trial will be conducted. We cannot assure you that the FDA will deem each of the clinical trial sites to have complied with applicable laws and regulations, and negative inspection results could significantly delay or prevent any potential approval for tebipenem HBr. If the FDA revokes or alters its agreement under the SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval, which could materially adversely affect our business, financial condition and results of operations. In March 2020, the FDA granted orphan drug designation for SPR720. We may seek orphan drug designation for certain of our other product candidates. We may not be able to obtain or maintain orphan drug designations for any of our other product candidates, and we may be unable to take advantage of the benefits associated with orphan drug designation, including the potential for market exclusivity. Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals in the United States, or a patient population of greater than 200, 000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. There can be no assurance that the FDA will grant orphan designation for any indication for which we apply. In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. In addition, if a product candidate that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, it is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. Even though we have obtained orphan drug designation for SPR720 and may seek orphan drug designation for other product candidates in the future, there is no assurance that we will be the first to obtain marketing approval for NTM infection or for any particular rare indication. Further, even though we have obtained orphan drug designation for SPR720, or even if we obtain orphan drug designation for other product candidates, such designation may not effectively protect us from competition because different drugs can be approved for the same condition and the same drug can be approved for different conditions and potentially used off- label in the orphan indication. Even after an orphan drug is approved, the FDA can subsequently approve a competing drug for the same condition for several reasons, including, if the FDA concludes that the later drug is safer or more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. If approved for commercial marketing in the United States, our product candidates may face generic competition sooner than anticipated. Even if we are successful in achieving regulatory approval to commercialize a product candidate, it may face competition from generic products earlier or more aggressively than anticipated, depending upon how well our future products perform in the United States prescription drug market. In addition to creating the 505 (b) (2) NDA pathway, the Hatch-Waxman Amendments to the FDCA authorized the FDA to approve generic drugs that are the same as drugs previously approved for marketing under the NDA provisions of the statute pursuant to ANDAs. An ANDA relies on the preclinical and clinical testing conducted for a previously approved **reference listed drug (“** RLD ~~,~~ **”)** and must demonstrate to the FDA that the generic drug product is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug and also that it is “ bioequivalent ” to the RLD. The FDA is prohibited by statute from approving an ANDA when certain marketing or data exclusivity protections apply to the RLD. If the FDA ultimately approves tebipenem HBr for the treatment of cUTI, including pyelonephritis, caused by certain microorganisms in adult patients who have limited oral treatment options, we expect that it will be designated by the agency as an RLD and that it will be eligible for five- year new chemical entity exclusivity under the Hatch- Waxman provisions of the FDCA. This exclusivity period would

block FDA from approving either a subsequent ANDA or 505 (b) (2) NDA that references our future NDA, if approved. The ~~QIDP~~ **qualified infectious disease product** designation granted by FDA to this drug product and indication also make it eligible for a further five- year extension of that Hatch- Waxman exclusivity. We cannot predict the interest of potential generic competitors in the future market for such an approved treatment for cUTI, whether someone will attempt to invalidate our period of exclusivity or otherwise force the FDA to take other actions, or how quickly others may seek to come to market with competing products after the applicable exclusivity period ends. Future product candidates may also receive marketing exclusivity under the FDCA after approval that may similarly be subject to challenge or uncertainty. If we or our partners are unable to obtain marketing approval in international jurisdictions, we will not be able to market our product candidates abroad. In order to market and sell our product candidates in the European Union and many other jurisdictions, we or our partners must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The approval procedure varies among countries and can involve additional testing. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Further, in April 2023, the European Commission issued a proposal to revise and replace the existing general pharmaceutical legislation. If adopted and implemented as currently proposed, these revisions will significantly change several aspects of drug development and approval in the European Union. The time required to obtain approval from regulatory authorities in other countries may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or our partners may not obtain approvals from regulatory authorities outside the United States on a timely basis or at all. If we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continuing regulatory review, which may result in significant additional expense. Our product candidates, if approved, could be subject to restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if approved. Any product candidate for which we obtain marketing approval will also be subject to ongoing regulatory requirements for labeling, packaging, storage, distribution, advertising, promotion, record keeping and submission of safety and other post- market information. For example, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs. As such, we and our contract manufacturers will be subject to continual review and periodic inspections to assess compliance with cGMPs. We and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and to comply with requirements concerning advertising and promotion for our products. In addition, even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed, may be subject to significant conditions of approval or may impose requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA closely regulates the post- approval marketing and promotion of drugs to ensure that drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling and regulatory requirements. The FDA also imposes stringent restrictions on manufacturers' communications regarding off- label use and if we do not restrict the marketing of our products only to their approved indications, we may be subject to enforcement action for off- label marketing. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us. In addition, if any product fails to comply with applicable regulatory requirements, a regulatory agency may: • issue warning letters, untitled letters or impose holds on clinical trials if any are still on- going; • mandate modifications to promotional materials or require provision of corrective information to healthcare practitioners; • impose restrictions on the product or its manufacturers or manufacturing processes; • impose restrictions on the labeling or marketing of the product; • impose restrictions on product distribution or use; • require post- marketing studies or clinical trials; • require withdrawal of the product from the market; • refuse to approve pending applications or supplements to approved applications that we submit; • require recall of the product; • require entry into a consent decree, which can include imposition of various fines (including restitution or disgorgement of profits or revenue), reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance; • suspend or withdraw marketing approvals; • refuse to permit the import or export of the product; • seize or detain supplies of the product; or • issue injunctions or impose civil or criminal penalties. The FDA' s policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. Our relationships with customers and third- party payors will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, physicians and third- party payors will play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Our future arrangements with third- party payors and customers will expose us to broadly

applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval and reimbursement. These laws and regulations include, for example, the false claims and anti- kickback statutes and regulations. At such time as we market, sell and distribute any products for which we obtain marketing approval and reimbursement, it is possible that our business activities could be subject to challenge under one or more of these laws and regulations. Restrictions under applicable federal and state healthcare laws and regulations include the following: • the federal healthcare Anti- Kickback Statute, among other things, prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federally funded healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate the statute in order to have committed a violation. In addition, the government may assert that a claim that includes 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 Act; • the federal False Claims Act imposes criminal and civil penalties, which can be enforced by private citizens through civil whistleblower and qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or for making any false statements relating to healthcare matters; as in the case of the federal healthcare Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate the statute in order to have committed a violation; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, also imposes obligations on certain covered entities as well as their business associates that perform services involving the use or disclosure of protected health information, including mandatory contractual terms, with respect to safeguarding the privacy and security of protected health information, and requires notification to affected individuals and regulatory authorities of certain breaches of security of protected health information; • the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; • the federal Physician Payments Sunshine Act requires manufacturers of drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to the DHHS, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, chiropractors and certain advanced non- physician health care practitioners), teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; • state and federal consumer protection laws, including the Federal Trade Commission Act, govern the collection, use, disclosure and protection of health and other personal information and could apply to our operations and the operations of our collaborators; and • analogous state laws and regulations, such as state anti- kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers, and some state laws require pharmaceutical companies to implement compliance programs and to track and report gifts, compensation and other remuneration provided to physicians, in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information. State laws also govern the privacy and security of health information in some circumstances, and many such state laws differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. We will be required to spend substantial time and money to ensure that our business arrangements with third parties, and our business generally, comply with applicable healthcare laws and regulations. Even then, governmental authorities may conclude that our business practices, including arrangements we may have with physicians and other healthcare providers, do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If governmental authorities find that our operations violate 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, imprisonment, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could affect our operations and business. The extent to which future legislation or regulations, if any, relating to healthcare fraud and abuse laws or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain. Recently enacted and future policies and legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the reimbursement made for any product candidate for which we receive marketing approval. The pricing and reimbursement environment may become more challenging due to, among other reasons, policies advanced by the presidential administration, federal agencies, new healthcare legislation passed by the United States Congress or fiscal challenges faced by all levels of government health administration authorities. Among policy makers and payors in the United States and foreign countries, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of any products for which we obtain marketing approval, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. Resulting legislative, administrative, or policy changes from payors may reduce payments for any products for which we obtain marketing approval and could affect future revenues. The ACA became law in the United States in March 2010 with the goals of broadening access to health insurance, reducing or constraining the growth of healthcare spending, enhancing remedies against fraud and abuse, adding new transparency requirements for the health care and health insurance industries and

imposing additional health policy reforms. Provisions of ACA may negatively affect our future revenues. For example, the ACA requires, among other things, that annual fees be paid by manufacturers for certain branded prescription drugs, that manufacturers participate in a discount program for certain outpatient drugs under Medicare Part D, and that manufacturers provide increased rebates under the Medicaid Drug Rebate Program for outpatient drugs dispensed to Medicaid recipients. The ACA also addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for line extensions and expands oversight and support for the federal government' s comparative effectiveness research of services and products. Beginning on April 1, 2013, Medicare payments for all items and services under Part A and B, including drugs and biologicals, and most payments to plans under Medicare Part D were reduced by 2 %, or automatic spending reductions, required by the Budget Control Act of 2011 (~~"~~ **"** BCA ~~"~~ **"**), as amended by the American Taxpayer Relief Act of 2012. The BCA requires sequestration for most federal programs, excluding Medicaid, Social Security, and certain other programs. The BCA caps the cuts to Medicare payments for items and services and payments to Part D plans at 2 %. As long as these cuts remain in effect, they could adversely affect payment for our product candidates, if approved for commercial marketing. 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. Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. There have been several United States Congressional inquiries and proposed bills 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. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U. S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate PBMs and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The Federal Trade Commission in mid- 2022 also launched sweeping investigations into the practices of the PBM industry **, and published interim reports with its finding in mid- 2024 and January 2025,** that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements ~~. During~~ **, including in** the current **2025- 2026** congressional session **. During the previous congressional session** , numerous **bipartisan** PBM reforms **were** ~~are being~~ considered in both the Senate and the House of Representatives; they include diverse legislative proposals such as eliminating rebates; divorcing service fees from the price of a drug, discount, or rebate; prohibiting spread pricing; limiting administrative fees; requiring PBMs to report formulary placement rationale; promoting transparency. Significant efforts to change the PBM industry as it currently exists in the **United States** ~~U. S.~~ may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical developers like us **. In September 2023, the FTC issued a policy statement articulating its view that certain " improper " patent listings by drug developers in FDA' s Orange Book represent an unfair trade practice and indicated that industry should be prepared for potential enforcement actions based on its analysis. The FTC followed that action in November 2023 by publicly calling out over 100 " improper " patent listings made by ten large pharmaceutical companies and initiating an FDA administrative process with respect to those patents. The controversy regarding the appropriateness of listing such patents has led to numerous lawsuits alleging anticompetitive conduct by biopharmaceutical companies. It remains to be seen whether the FTC under the Trump Administration will continue to prioritize the policy issue of " improper " patent listings or whether Congress may take any legislative actions related to this issue. Accordingly, regulatory and government interest in biopharmaceutical industry business practices continues to expand and pose a risk of uncertainty** . Further, in August 2022, President Biden signed into the law the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. A manufacturer of drugs covered by Medicare Parts B or D must now pay a rebate to the federal government if their drug product' s price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS **is** ~~will also negotiate~~ **negotiating** drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities, ~~including with its publication of the first list of 10 Medicare Part D drugs for negotiation in September 2023 and~~ entering into agreements to conduct negotiations with the relevant manufacturers of those selected drugs in October 2023 **and ultimately announcing the first round of negotiated prices for the first 10 drugs in August 2024; those negotiated " maximum fair prices " will be effective as of January 1, 2026 (payment year 2026). CMS is currently engaged in its second round of negotiations and published the next 15 drugs selected for negotiation in January 2025** . However, the impact of this program on the biopharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e. g., the U. S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. ~~Those~~ -- **The outcome of such ongoing** lawsuits ~~are currently ongoing~~ **, as well as potential legislative changes enacted by Congress or programmatic changes implemented at CMS by the Trump Administration, may impact the IRA drug price negotiation program in the future** . Legislative and regulatory proposals also have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes

will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the effect of such changes on the marketing approvals of our product candidates, if any, may be. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services. If we successfully commercialize one of our product candidates, failure to comply with our reporting and payment obligations under ~~United States~~ **U. S.** governmental pricing programs could have a material adverse effect on our business, financial condition and results of operations. If we participate in the Medicaid Drug Rebate Program if and when we successfully commercialize a product candidate, we will be required to report certain pricing information for our product to the Centers for Medicare & Medicaid Services, the federal agency that administers the Medicaid and Medicare programs. We may also be required to report pricing information to the United States Department of Veterans Affairs. If we become subject to these reporting requirements, we will be liable for errors associated with our submission of pricing data, for failure to report pricing data in a timely manner, and for overcharging government payers, which can result in civil monetary penalties under the Medicaid statute, the federal civil False Claims Act, and other laws and regulations. Additionally, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive healthcare provisions and amendments to existing laws, which includes a requirement that all manufacturers of drug products covered under Medicare Part B report the product' s ASP to DHHS beginning on January 1, 2022, subject to enforcement via civil money penalties. **Increasingly there are state laws and regulations that require prescription drug price reporting or impose other restrictions designed to control pharmaceutical product pricing, such as price or patient reimbursement constraints and discounts.** Our employees, independent contractors, principal investigators, contract research organizations, consultants or vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, principal investigators, contract research organizations, consultants or vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates: FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; manufacturing standards; federal and state healthcare fraud and abuse laws and regulations; or laws that require the true, complete and accurate reporting of financial information or data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished potential profits and future earnings, and curtailment of our operations, any of which could adversely affect our business, financial condition, results of operations or prospects. ~~Inadequate~~ **Disruptions of** funding for the FDA, the SEC and other government agencies **caused by funding shortages, mass layoffs, or global health concerns** could hinder their ability to hire and retain key leadership and other personnel, prevent our product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business relies, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the United States government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities **during that period. In early 2025, following the inauguration of President Trump, the Trump Administration began terminating federal government employees, including at the FDA. The impact of mass layoffs at the agency and other governmental offices with which we interact is unclear at this time. However, it is expected that with a proposed reduction in staff of up to 50 %, the FDA in the future may be unlikely to meet its application review goals or to continue to be available for timely interactions with medical product developers. It is currently unclear how the U. S. biopharmaceutical industry will be affected by the Trump Administration' s major changes to the FDA and the federal government as a whole. Separately, during the 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 of domestic facilities where feasible, the agency has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates, and any resurgence of the**

virus or emergence of new infectious disease outbreaks may lead to future inspectional delays. Regulatory authorities outside the United States may adopt similar policy measures in response to emerging infectious disease outbreaks, epidemics, or pandemics . If a prolonged government shutdown **or slowdown** occurs **, or if global health concerns similar to COVID- 19 prevent the FDA or other regulatory agencies from conducting their regular inspections, review, or other regulatory activities** , it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations **. Further, three decisions from the U. S. Supreme Court issued in July 2024 may lead to an increase in litigation against regulatory agencies that could create uncertainty and thus negatively impact our business. The first decision overturned established precedent that required courts to defer to regulatory agencies' interpretations of ambiguous statutory language. The second decision overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. The third decision extended the statute of limitations within which entities may challenge agency actions. These cases may result in increased litigation by industry against regulatory agencies, including but not limited to the FDA and SEC, and may impact how such agencies choose to pursue enforcement and compliance actions. However, the specific, lasting effects of these decisions, which may vary within different judicial districts and circuits, is unknown. We also cannot predict the extent to which FDA and SEC regulations, policies, and decisions may become subject to increasing legal challenges, delays, and changes** . Risks Related to Employee Matters and Managing Growth Our future success depends on our ability to retain our ~~chief executive officer and other~~ key executives and to attract, retain and motivate qualified personnel. Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of ~~Satyavrat Shukla, our President and Chief Executive Officer, as well as the other~~ principal members of our management, scientific and clinical team. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time. **On October 29, 2024, we implemented a restructuring plan that will reduce our workforce by approximately 39 %. While we have confidence in our remaining employees, including our leadership team, and the Board of Directors, the uncertainty inherent in this ongoing restructuring may be difficult to manage, may cause concerns from third parties with whom we do business, and may increase the likelihood of turnover of other key officers and employees. Continued disruption caused by the transition or by the loss of ongoing services of any qualified scientific and management personnel could delay or prevent the successful development of our product candidates.** If we lose one or more of our ~~other~~ executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited **. We undertook internal restructuring activities that could result in disruptions to our business or otherwise materially harm our results of operations or financial condition, and we may not realize the expected benefits from our restructuring and we may incur additional costs implementing it or other difficulties. On October 29, 2024, we announced a restructuring plan and implemented a workforce reduction. There can be no assurance that our restructuring will achieve the cost savings, operating efficiencies or other benefits that we may initially expect. Restructuring activities may also result in a loss of continuity, accumulated knowledge and inefficiency during transitional periods and thereafter. Further, internal restructurings can require a significant amount of time and focus from management and other employees, which may divert attention from operations. Additionally, our restructuring may result in unexpected expenses or liabilities and / or write- offs. If our restructuring fails to achieve some or all of the expected benefits therefrom, our cash resources may not last as long as estimated and our business, results of operations and financial condition could be materially and adversely affected** . If foreign approvals are obtained, we will be subject to additional risks in conducting business in international markets. Even if we are able to obtain approval for commercialization of a product candidate in a foreign country, we will be subject to additional risks related to international business operations, including: • potentially reduced protection for intellectual property rights; • the potential for so- called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally; • unexpected changes in tariffs, trade barriers and regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • workforce uncertainty in countries where labor unrest is more common than in the United States; • production shortages resulting from any events affecting a product candidate and / or finished drug product supply or manufacturing capabilities abroad; • business interruptions resulting from geo- political ~~actions~~ **conflicts** , including war and terrorism, health epidemics or natural disasters, including earthquakes, hurricanes, typhoons, floods and fires; and • failure to comply with Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act. These and other risks may materially adversely affect our ability to attain or sustain revenue from international markets. Risks Related to Our Common Stock The price of our common stock **has been and, in the future,** may **continue to** be volatile ~~and fluctuate substantially~~ **whether**

related or unrelated to our operations , which could result in ~~substantial losses~~ **a decline in value** for our stockholders. Our stock price may be 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. As a result of this volatility, our stockholders may not be able to sell their shares at or above the price they paid for their shares. The market price for our common stock may be influenced by many factors, including: • the success of existing or new competitive products or technologies; • the timing of clinical trials of our product candidates; • results of clinical trials of any of our product candidates; • 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; • the perception of the pharmaceutical and biotechnology industry by the public, legislatures, regulators and the investment community; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key personnel; • the level of expenses related to any of our product candidates or clinical development programs; • the results of our efforts to develop, in- license or acquire 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. In addition, the stock market has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management' s attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation. ~~We have in the past failed to satisfy certain continued listing requirements of~~ **An active trading market for our common stock may never develop or be sustained. Although our common stock is listed on** the Nasdaq ~~Global Select~~ **GS, an active trading** ~~Market~~ **market** ~~and~~ **for our shares may never develop or be sustained. As a result, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares, or at all. Our shares of common stock** could ~~fail to satisfy~~ **be delisted from** ~~those --~~ **the Nasdaq GS** ~~requirements again in the future~~ , which could ~~negatively affect~~ **result in, among** ~~the~~ **other** ~~market~~ **things, a decline in the** price of our common stock ~~, our~~ **and less** liquidity ~~and~~ **for** our **stockholders** ~~ability to raise capital. Our potential failure to meet the continued listing requirements of Nasdaq Global Select Market in the future could result in a delisting of our common stock~~ . Our common stock is listed on the Nasdaq ~~Global Select Market (" Nasdaq~~ GS ~~")~~ , which imposes, among other requirements, a minimum $ 1. 00 per share bid price requirement for continued inclusion on the Nasdaq GS pursuant to Nasdaq Listing Rule 5450 (a) (1) (the " Bid Price Requirement "). The closing bid price for our common stock must remain at or above $ 1. 00 per share to comply with the Bid Price Requirement for continued listing. On ~~August 8~~ **February 25** , ~~2022~~ **2025 ,** we received a deficiency letter (the " Notice ") from the Listing Qualifications Department of ~~the~~ Nasdaq ~~Stock Market~~ , **or the** ~~LLC (" Nasdaq ") notifying~~ **Staff, informing** us that ~~, for~~ **we were not in compliance with** the ~~preceding~~ **continued listing requirements of the Nasdaq GS because the bid price for our common stock had closed below $ 1. 00 per share for** 30 consecutive trading days ~~, the closing bid price of our common stock was below the Bid Price Requirement~~ . In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), we ~~had~~ **have** until ~~February 6~~ **August 25** , ~~2023~~ **2025 (the " Compliance Date "),** to regain compliance with the Bid Price Requirement. ~~On October 6~~ **According to the Notice** , **if at any time before August 25,** ~~2022~~ **2025** , ~~we received a letter from Nasdaq notifying us that~~ the closing bid price of our common stock ~~was~~ **is** at least $ 1. 00 per share for a minimum of 10 consecutive ~~trading~~ **business** days ~~and~~ **, Nasdaq will provide written notification** that we ~~had regained~~ **have achieved** compliance with the Bid Price Requirement ~~. Our~~ **and our** common stock **will** ~~continues~~ **continue** to be eligible for listing on the Nasdaq GS **. If we do not regain compliance with the Bid Price Requirement by the Compliance Date, we may be eligible for an additional 180 day compliance period under the following circumstances. To qualify, we would need to transfer the listing of the common stock to the Nasdaq Capital Market, provided that we meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards, with the exception of the Bid Price Requirement. To effect such a transfer, we would also need to pay an application fee to Nasdaq and will need to provide written notice to Nasdaq of our intention to cure the deficiency during the additional compliance period by effecting a reverse stock split, if necessary. As part of its review process, Nasdaq would make a determination of whether it believes we will be able to cure this deficiency. If Nasdaq concludes that we will not be able to cure the deficiency, or if we do not cure the deficiency within such additional 180 day compliance period, Nasdaq will provide written notification to us that our common stock will be subject to delisting. At that time, we may appeal Nasdaq' s delisting determination to a Nasdaq Listing Qualifications Panel (the " Panel "). However, there can be no assurance that, if we receive a delisting notice and appeal the delisting determination by Nasdaq to the Panel, such appeal would be successful** . There can be no assurance that we will be able to keep the closing bid price above $ 1. 00 per share **for the required 10 consecutive trading days by August 25, 2025** . ~~If~~ **Further, if** we ~~fail~~ **are unable** to ~~satisfy~~ **maintain the closing bid price at $ 1. 00 for the required period,** ~~the~~ **there** ~~continued listing requirements of Nasdaq GS, including~~ **is no guarantee that we will regain compliance with** the Bid Price Requirement ~~, Nasdaq may provide~~ **. There is no guarantee that a reverse stock split would be approved by the stockholders or that a reverse stock split would allow** us ~~with another deficiency letter regarding the continued listing requirement. If we are unable~~ to regain compliance with the **Bid Price Requirement. Any potential** ~~Nasdaq Listing Rules in the future, Nasdaq may take steps to delist~~ **delisting of** our common stock ~~. Such~~ **could have** a **material adverse effect on the market for, and liquidity and price of, our**

common stock and would adversely affect our ability to raise capital on terms acceptable to us, or at all. ~~delisting~~ **Delisting** from ~~the~~ Nasdaq GS could **also have other negative results, including, without limitation, the potential loss of confidence by investors, customers and employees and fewer business development opportunities. Such a delisting from the Nasdaq GS would also** make trading our common stock more difficult for **stockholders** ~~investors, potentially leading to declines in our share price and liquidity. If our common stock is delisted by the Nasdaq GS, our common stock may be eligible to trade on the Nasdaq Capital Market or an over- the- counter quotation system, where an investor may find it more difficult~~ to sell ~~our stock or obtain accurate quotations as to the~~ **their shares in the public** market ~~value of our common stock. We cannot assure you that our common stock, if delisted from the Nasdaq GS, will be listed on another national securities exchange or quoted on an over- the counter quotation system~~. We intend to actively monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to maintain **compliance with the minimum bid price requirement under the Nasdaq Listing Rules. We intend to actively monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to regain** compliance with the minimum bid price requirement under the Nasdaq Listing Rules. If securities or industry analysts do not 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 relies in part on the research and reports that securities or industry analysts publish about us or our business. If few analysts provide coverage of us, the trading price of our stock would likely decline. If one or more of the analysts covering our business downgrade our stock or change their opinion of our stock, our share price would likely decline. In addition, if one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. ~~We can issue~~ **Unstable global economic** and **political conditions** ~~have issued shares of preferred stock~~, ~~which may~~ **including economic uncertainty tied to volatility in interest rates and inflation, credit and financial market instability, and uncertainty related to ongoing geopolitical conflicts, could** adversely affect ~~the rights of holders of~~ our ~~common~~ **business, financial condition,** stock **price** ~~. Our Amended and Restated Certificate of Incorporation, as amended, authorizes us to issue up to 10, 000, 000 shares of preferred stock with designations, rights and preferences determined from time- to- time by our board of directors. Accordingly, our board of directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting or other rights superior to those of holders of our common stock. For example, an~~ **and** ~~issuance of shares of preferred stock~~ **ability to raise capital. Unstable global economic and political conditions, including economic uncertainty tied to volatility in interest rates and inflation, credit and financial market instability, and uncertainty related to ongoing geopolitical conflicts,** could ~~: •~~ adversely affect ~~the voting power of the holders of~~ our ~~common~~ **business, financial condition,** stock ~~; •~~ **price and ability to raise capital. The global economy, in particular the financial markets, have recently experienced significant disruption and volatility, including without limitation, as a result of volatility in interest rates and inflation, capital markets volatility, currency rate fluctuations, volatility in commodity prices, decline in consumer confidence and economic growth, supply chain disruptions, banking disruptions, and uncertainty resulting from geopolitical events, including trade wars, civil and political unrest, wars and other armed conflicts. In addition,** ~~make~~ **market , interest rate, and inflation volatility may increase our cost of financing or restrict our access to potential sources of future capital. Furthermore, our stock price may further decline due in part to the volatility of the stock market and any general economic downturn. If the disruption and volatility persist or heighten,** it **may impact** ~~more difficult for a third party to gain control of us; • discourage bids for~~ our ~~common~~ **ability to raise sufficient additional capital on agreeable terms, if at all. If we are unable to raise sufficient additional capital, our business, financial condition,** stock **price and results** ~~at a premium; • limit or eliminate any payments that the holders~~ of **operations** ~~our common stock~~ could **be** ~~expect to receive upon our liquidation; or • otherwise~~ adversely ~~affect~~ **affected , and we will need to implement cost reduction strategies, which could include delaying, reducing or altogether terminating both internal and external costs related to our operations and research and development programs. In addition, political developments impacting government spending and international trade, including changes in trade agreements, trade disputes, tariffs and investment restrictions, such as the ongoing trade dispute between the United States and China, may negatively impact markets and cause weaker macroeconomic conditions. These global economic and political factors could also strain certain of our suppliers and manufacturers, possibly resulting in supply disruptions or increased raw material or manufacturing costs, or adversely impacting** ~~the~~ **their ability to manufacture clinical trial materials for our product candidates. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic and geopolitical climate and financial** market ~~price~~ **conditions could adversely impact** ~~or~~ **our business** ~~our common stock. As of December 31, 2023, all of our previously issued Series A Convertible Preferred Stock, Series B Convertible Preferred Stock, Series C Convertible Preferred Stock, and Series D Convertible Preferred stock has been converted into shares of our common stock. If any future holders of our shares of preferred stock convert their shares into common stock, existing holders of our common stock will experience dilution~~ . We have broad discretion in the use of our cash reserves and may not use them effectively. Our management has broad discretion in the application of our cash reserves and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash reserves in a manner that does not produce income or that loses value. We are a smaller reporting company and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors. We are subject to Section 404 of The Sarbanes- Oxley Act of 2002 (**" "** Section 404 **" "**) and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. However, for so long as we remain a **" "** smaller reporting company **" "** (**" "** SRC **" "**)

and non- accelerated filer, we intend to take advantage of certain exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we do not meet the definition of a SRC and non- accelerated filer or, if prior to 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 controls over financial reporting. We could continue to qualify as a SRC and non- accelerated filer if the market value of our common stock held by non- affiliates is below $ 75. 0 million (or $ 700. 0 million if our annual revenue is less than $ 100. 0 million) as of June 30 in any given year. We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives and corporate governance practices. As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. Sarbanes- Oxley, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq GS and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time- consuming and costly. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our ~~board~~ **Board** of ~~directors~~ **Directors** . These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Failure to maintain effective internal controls in accordance with Section 404 of Sarbanes- Oxley in the future could have a material adverse effect on our ability to produce accurate financial statements and on our stock price. Section 404 of Sarbanes- Oxley requires us, on an annual basis, to review and evaluate our internal controls. To maintain compliance with Section 404, we are required to document and evaluate our internal control over financial reporting, which is both costly and challenging. We will need to continue to dedicate internal resources, continue to engage outside consultants and follow a detailed work plan to continue to assess and document the adequacy of internal control over financial reporting, continue to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. A significant portion of our total outstanding shares may be sold into the market at any time, which 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. Our outstanding shares of common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act ~~of 1933~~ , or to the extent that such shares have already been registered under the Securities Act and are held by non- affiliates of ours. Moreover, holders of a substantial number of shares of our common stock 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. We also have registered all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline. 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 or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the operation, development and growth of our business. To the extent that we enter into any future debt agreements, the terms of such agreements may also preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future. Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our Amended and Restated Certificate of Incorporation, as amended, and Amended and Restated Bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that our stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. 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~~ **Board** of ~~directors~~ **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~~ **Board** of ~~directors~~ **Directors** . Among other things, these provisions: • establish a classified ~~board~~ **Board** of ~~directors~~ **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~~ **Board** of ~~directors~~ **Directors** ; • limit the manner in which stockholders can remove directors from our ~~board~~ **Board** of ~~directors~~ **Directors** ; • establish advance notice requirements for nominations for election to our ~~board~~ **Board** of ~~directors~~ **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~~ **Board** of ~~directors~~ **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~~ **Board** of ~~directors~~ **Directors** ; and • require the approval of the holders of at least 75 % of the votes that all of our stockholders would be entitled to cast to amend or repeal certain provisions of our Amended and Restated Certificate of Incorporation, as amended, or Amended and Restated Bylaws. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the ~~"~~ **“** DGCL ~~"~~ **”**), which prohibits 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. In addition, our Amended and Restated Certificate of Incorporation, as amended, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware will be the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our Amended and Restated Certificate of Incorporation, as amended, or our Amended and Restated Bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rule and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. This choice of forum provision may limit a stockholder’ s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our Amended and Restated Certificate of Incorporation, as amended, to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition. Provisions in our ~~charter~~ **Amended and Restated Certificate of Incorporation, as amended,** and other provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock **. We have received a “ Wells Notice ” from the SEC contemplating a civil enforcement action, which could have a material adverse effect on our business, financial condition and results of operations, prospects, and / or our stock price. On January 9, 2025, we responded to a “ Wells Notice ” from the staff of the Boston Regional Office (the “ Staff ”) of the SEC regarding its preliminary determination to recommend a civil enforcement action or administrative proceeding against us, its former Chief Executive Officer and Chairman of the Board of Directors, Ankit Mahadevia, M. D. (“ Dr. Mahadevia ”), and its former Chief Financial Officer and President and Chief Executive Officer, Satyavrat “ Sath ” Shukla (“ Mr. Shukla ”), relating to certain public disclosures by us from March 31, 2022 leading up to our announcement on May 3, 2022 that we had determined to cease commercialization of tebipenem HBr based on feedback from the FDA, and whether our disclosures may have violated the federal securities laws (the “ Investigation ”). A Wells Notice is neither a formal charge of wrongdoing nor a final determination that the recipient has violated any law, but is a preliminary determination by the Staff to recommend to the SEC Commissioners that a civil enforcement action or administrative proceeding be brought against the recipients. If the SEC were to authorize an action against us and / or any of the identified individuals, it may seek an injunction or cease- and- desist order against future violations of provisions of the federal securities laws, the imposition of civil monetary penalties, disgorgement or other equitable relief within the SEC’ s authority, or any combination of the foregoing. The SEC could also seek an order barring each identified individual from serving as an officer or director of a public company for a specified period of time. We, Dr. Mahadevia and Mr. Shukla are cooperating with the SEC and have made a submission in response to the Wells Notice explaining why an enforcement action would not be appropriate. We cannot predict the results of the Investigation and the Wells Notice process and any corresponding enforcement action against us and / or any of the identified individuals, and the costs, timing and other potential consequences of responding and complying therewith with any certainty. The Investigation, and the Wells Notice process continues to be expensive and disruptive, and we are subject to indemnifying each of the individuals for their costs associated with the Wells Notices. Our insurance, to the extent maintained, may not cover all claims that may be asserted against us or the specified individuals, and we are unable to predict how long the Investigation will continue. An unfavorable outcome may have an adverse impact on our business, financial condition and results of operations, prospects, or our stock price. Any proceeding could also negatively impact our reputation among our stakeholders** . We may become involved in securities litigation that could divert management’ s attention and harm the company’ s business, and insurance coverage may not be sufficient to cover all costs and damages. In the past, securities litigation has often followed certain significant business ~~transactions~~ **activities** , such as the announcement of a strategic restructuring, or the announcement of negative events, such as negative results from clinical trials. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management’ s attention and resources, which could adversely affect our business and cash resources and our ability to execute on our partnership with GSK to eventually commercialize tebipenem HBr, or the ultimate value our stockholders receive in such partnership or other opportunity.