

## Risk Factors Comparison 2025-03-12 to 2024-03-28 Form: 10-K

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In evaluating our business, you should carefully consider the following risks, as well as the other information contained in this Annual Report on Form 10- K. These risk factors could cause our actual results to differ materially from those contained in forward- looking statements we have made in this Annual Report on Form 10- K and those we may make from time to time. If any of the following risks actually occurs, our business, financial condition and operating results could be harmed. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business. Risks Relating to Our Financial Condition and Need for Additional Capital We may not be able to realize the benefits we expect under the GSK License Agreement if we are not able to develop ibrexafungerp. Our ability to generate revenues under the GSK License Agreement is dependent upon our ability to further develop ibrexafungerp. The risks described below with respect to ibrexafungerp will continue to be risks for us as they may impede our ability to receive some or all of the development, regulatory, commercial and sales milestones, and royalties, contemplated by the GSK License Agreement, which would materially and adversely affect our business and operating results. We have a limited history of profitability, we have only one product approved for commercial sale that is licensed to GSK and is subject to a product recall, and to date we have generated limited revenue from product sales. As a result, our ability to curtail our losses and sustain profitability is unproven. We do not expect to be profitable in the foreseeable future. We incurred net losses in each year since our inception except for ~~net income of \$ 67. 0 million for~~ the year ended December 31, 2023, **which was** primarily due to the \$ 90. 0 million upfront payment received under the GSK License Agreement **in May 2023**. As of December 31, ~~2023~~ **2024**, we had an accumulated deficit of approximately \$ ~~355~~ **376. 2** million. On a prospective basis, our strategic focus, along with the commitment of our financial resources, will be directed towards the development of **SCY- 247** and ibrexafungerp. We had cash, cash equivalents, and investments of \$ ~~98~~ **75. 0** million as of December 31, ~~2023~~ **2024**. We have suffered substantial losses from operations since inception and will require additional financing. We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially as we: • conduct ongoing and initiate new clinical trials; • maintain, expand and protect our intellectual property portfolio; • hire additional clinical, quality control and scientific personnel; • maintain and create additional infrastructure to support our operations as a public company; and • develop in- house product candidates or seek to in- license product candidates from third- parties. In addition, our expenses could increase if we are required by the U. S. Food and Drug Administration, or the FDA, to perform studies in addition to, or that are larger than, those that we currently expect. As a result of the foregoing, we expect to experience net losses and negative cash flows from operations for the foreseeable future, and we are unable to predict when, or if, we will be able to achieve profitability. Our losses and negative cash flows have had, and will continue to have a material adverse effect on our stockholders' equity, financial position and statement of operations. We expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance. Our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter to quarter or year to year due to a variety of factors, many of which are beyond our control. The following factors relating to our business, as well as factors described elsewhere in this report, may contribute to these fluctuations: • the costs associated with completing the ongoing **and anticipated** clinical studies for ibrexafungerp **and SCY- 247**, which are difficult for us to predict, **including the potential costs associated with the anticipated resumption of the Phase 3 MARIO study if the clinical hold is lifted**; • any delays in regulatory review and approval of ibrexafungerp; • delays in the timing of submission of any new drug application, or NDA, or supplement thereto, as well as commencement, enrollment and the timing of clinical testing, of any product candidates we may seek to develop; • market acceptance of BREXAFEMME and any future product candidates for which we obtain FDA approval; • changes in regulations and regulatory policies; • competition from existing products or new products that may emerge; • the ability of patients or healthcare providers to obtain coverage of, or sufficient reimbursement for, any products we are able to develop; • our ability to establish or maintain collaborations, licensing or other arrangements; • costs related to, and outcomes of, potential litigation; • potential product liability claims; and • potential liabilities associated with hazardous materials. Due to the various factors mentioned above, and others, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance. Further, any financial projections we make are made as of the date we make them are subject to these risks and uncertainties, and these financial projections may not be realized. We will continue to require substantial additional capital, and if we are unable to raise capital when needed we would be forced to delay, reduce or eliminate our development program for ibrexafungerp and our planned development for SCY- 247. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. If the FDA requires that we perform additional studies beyond those that we currently expect, our expenses could increase beyond what we currently anticipate, the timing of the submission of our planned NDAs could be delayed, and any potential product approval could be delayed. We may need to raise additional funds from additional issuances of equity and / or debt securities or otherwise obtain funding through strategic alliances or collaborations with third parties. In any event, we will require additional capital to complete development of, to seek regulatory approval for and, if approval is obtained, to commercialize and any product candidates we may seek to develop. When we are required to secure additional financing, the additional fundraising efforts may divert our management from our day- to- day activities, which may adversely affect our ability to develop ibrexafungerp and any product candidates we may seek to develop. In addition, we cannot guarantee that financing will be available in sufficient

amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to: • significantly delay, scale back or discontinue the development or commercialization of and any product candidates we may seek to develop; • seek strategic alliances for research and development programs at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or • relinquish or license on unfavorable terms our rights to any product candidates that we otherwise would seek to develop or commercialize ourselves. If we are required to conduct additional fundraising activities and we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects. ~~Our operating activities may be restricted as a result of covenants related to the indebtedness under our senior convertible notes and we may be required to repay the notes and our loan payable in an event of default, which could have a materially adverse effect on our business. On March 7, 2019, we entered into a senior convertible note purchase agreement with Puissance Life Science Opportunities Fund VI (Puissance), pursuant to which we issued and sold to Puissance \$ 16 million of our 6.0% senior convertible notes due 2025. We may be required to repay the outstanding notes if an event of default occurs under the note purchase agreements. Under the note purchase agreements, an event of default will occur if, among other things: we fail to make payments under the note purchase agreement; we breach any of our covenants under the note purchase agreements, subject to specified cure periods with respect to certain breaches; or we or our subsidiaries become subject to bankruptcy, insolvency or reorganization proceedings. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In this case, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.~~ Unfavorable U. S. and global economic conditions could adversely affect our ability to access capital. Our ability to access capital could be adversely affected by general conditions in the U. S. and global economies, the U. S. and global financial markets and adverse geopolitical and macroeconomic developments. U. S. and global market and economic conditions have been, and continue to be, disrupted and volatile due to many factors, including component shortages and related supply chain challenges, geopolitical developments such as pandemics and conflicts and related sanctions, bank failures, and increasing inflation rates **and tariffs** and the responses by central banking authorities to control such inflation, among others. General business and economic conditions that could affect our ability to access capital include fluctuations in economic growth, debt and equity capital markets, liquidity of the global financial markets, access to our liquidity within the U. S. banking system, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our manufacturers and our suppliers operate. Risks Relating to the Development, Regulatory Approval and Commercialization of Our Product Candidates For Human Use We cannot be certain that ibrexafungerp will receive regulatory approval in the additional indications we are pursuing, and without regulatory approval it will not be possible to market ibrexafungerp for these indications. Regulatory approval is a lengthy, expensive and uncertain process and there is no guarantee that ibrexafungerp will be approved by the FDA for the additional indications we are pursuing. Our ability to generate additional significant revenue related to sales of ibrexafungerp by GSK, will depend on the successful development and regulatory approval of ibrexafungerp for indications in addition to the treatment of VVC and RVVC. We currently have one product approved ~~for sale~~ **which is subject to a product recall**, BREXAFEMME, which is approved for the treatment of VVC and for the reduction in the incidence of RVVC, and we cannot guarantee that we will obtain more marketable products. The development and commercialization of a product candidate, including preclinical and clinical testing, manufacturing, quality systems, labeling, approval, record- keeping, selling, promotion, marketing and distribution of products, is subject to extensive regulation by the FDA in the United States and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market product candidates in the United States until and unless we receive approval of an NDA or NDA supplement from the FDA. An NDA supplement has not been submitted for ibrexafungerp for the treatment of refractory invasive fungal infections, invasive pulmonary aspergillosis or any other indications. Obtaining approval of an NDA is a lengthy, expensive and uncertain process. An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate' s safety and effectiveness for each indication. The approval application must also include significant information regarding the chemistry, manufacturing and controls for the product. The product development and regulatory review process typically takes years to complete, involves numerous uncertainties and the potential for concerns to emerge late in the development process, and approval is never guaranteed. Even if a product is approved, the FDA may limit the indications for which the product may be used, require extensive warnings on the product labeling or require costly ongoing requirements for post- marketing clinical studies and surveillance or other risk management measures to monitor the safety or efficacy of the product candidate, including the imposition of a Risk Evaluation and Mitigation Strategy, or REMS. Markets outside of the United States also have requirements for approval of drug candidates with which we must comply prior to marketing. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure we will be able to obtain regulatory approval in other countries, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. Also, any regulatory approval of a product candidate, once obtained, may be withdrawn. If ibrexafungerp or any of our other wholly- owned or partnered product candidates do not receive timely regulatory approval, or fail to maintain that regulatory approval, we may not be able to generate sufficient revenue to become profitable or to continue our operations. Moreover, the submission of our NDA or the receipt of regulatory approval does not assure commercial success of any approved product. Although both the oral and IV formulations of ibrexafungerp have been granted Qualified Infectious Disease Product status and Fast Track designation, this does not guarantee that the length of the FDA review process will be significantly shorter than otherwise, or that ibrexafungerp will ultimately be approved by the FDA. We applied to the FDA for, and received, the designation of the oral tablet and the IV formulations of ibrexafungerp for

vulvovaginal candidiasis, invasive candidiasis and invasive aspergillosis as Qualified Infectious Disease Product (QIDP) under the Generating Antibiotic Incentives Now Act (GAIN Act). We also applied to the FDA for, and were granted, Fast Track designation for ibrexafungerp for these indications. Receipt of QIDP status and Fast Track designation in practice may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA or related GAIN Act exclusivity benefits. Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for ibrexafungerp or any future product candidates. We do not know whether our current clinical trials of ibrexafungerp **and SCY- 247** will be completed on schedule or at all, or whether any future clinical trials of ibrexafungerp or any future product candidates we may seek to develop will be allowed to commence or, if commenced, will be completed on schedule or at all. The commencement, enrollment and completion of clinical trials can be delayed for a variety of reasons, including:

- inability to reach agreements on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- difficulty identifying and engaging qualified clinical investigators;
- regulatory objections to commencing a clinical trial or proceeding to the next phase of investigation, including inability to reach agreement with the FDA or non- U. S. regulators regarding the scope or design of our clinical trials or for other reasons such as safety concerns that might be identified during preclinical development or early stage clinical trials;
- inability to identify and maintain a sufficient number of eligible trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care;
- inability to obtain institutional review board (or ethics review committee) approval to conduct a clinical trial at prospective sites;
- difficulty identifying, recruiting and enrolling eligible patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indication as product candidates we seek to commercialize;
- inability to retain patients in clinical trials due to the treatment protocol, personal issues, side effects from the therapy or lack of efficacy;
- inability to produce and / or obtain in a timely manner sufficient quantity of our products to satisfy the requirements of the clinical trials;
- inability to enroll patients, or slow down in the rate of enrolling patients, in clinical trials due to unforeseen natural disasters, public health crises, political crises and other catastrophic events or other events outside of our control, such as COVID- 19, which may cause participants to not want to participate in these trials or otherwise have any unnecessary contact with the medical community; and
- inability to obtain sufficient funding to commence a clinical trial.

In addition, a clinical trial may be suspended or terminated by us, our current or any future partners, an institutional review board, the FDA or other regulatory authorities due to a number of factors, including:

- failure by us, CROs or clinical investigators to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- failed inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- safety or efficacy issues or any determination that a clinical trial presents unacceptable health risks.

During an extension of our Phase 1 program for the intravenous formulation in healthy volunteers, aimed to expand the safety margin that would allow greater flexibility of dosing options in patients, we observed adverse events secondary to thrombi formation at site of IV infusion; or

- lack of adequate funding to continue the clinical trial due to unforeseen costs resulting from enrollment delays, requirements to conduct additional trials and studies, increased expenses associated with the services of our CROs and other third parties, or other reasons.

If we are required to conduct additional clinical trials or other testing of ibrexafungerp or any future product candidates we may seek to develop, we may be delayed in obtaining, or may not be able to obtain, marketing approval for these product candidates. In addition, if our current or any future partners have rights to and responsibility for development of ibrexafungerp or any future product candidates, they may fail to meet their obligations to develop and commercialize the product candidates, including clinical trials for these product candidates. Changes in regulatory requirements and guidance may occur and we or any of our partners may be required by appropriate regulatory authorities to amend clinical trial protocols to reflect these changes. Amendments may require us or any of our partners to resubmit clinical trial protocols to independent review boards for re- examination, which may impact the costs, timing or successful completion of a clinical trial. If we or any of our partners experience delays in the completion of, or if we or our partners terminate, clinical trials, the commercial prospects for ibrexafungerp and any future product candidates we may seek to develop will be harmed, and our ability to generate revenue from sales of these product candidates will be prevented or delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Clinical failure can occur at any stage of clinical development. Because the results of earlier clinical trials are not necessarily predictive of future results, any product candidate we or our current or potential future partners advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or our partners may decide, or regulators may require us, to conduct additional clinical or preclinical testing. In addition, data obtained from tests are susceptible to varying interpretations, and regulators may not interpret data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product application, or approval of a supplemental application to add a new indication or other changes, and flaws or shortcomings in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval, or approval of supplemental applications for new indications or other changes. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. If ibrexafungerp or any future product candidates are found to be unsafe or lack

efficacy, we or our collaborators will not be able to obtain regulatory approval for them and our business would be harmed. For example, if the results of our completed, ~~ongoing or planned Phase 2~~ and **current** Phase 3 clinical trials of ibrexafungerp do not achieve, to the satisfaction of regulators, the primary efficacy endpoints and demonstrate an acceptable level of safety, the prospects for approval of ibrexafungerp would be materially and adversely affected. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase 2 and Phase 3 clinical trials, even after seeing promising results in earlier clinical trials. 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 differences in trial protocols and design, differences in size and type of the patient populations, adherence to the dosing regimen and the rate of dropout among clinical trial participants. Further, the patients taking ibrexafungerp often have other significant medical issues, such as organ transplants, cancer or other conditions in which their immune systems are suppressed, which makes it difficult to measure the effect of ibrexafungerp in the presence of these medical issues. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any partners may conduct will demonstrate consistent and / or adequate efficacy and safety to obtain regulatory approval to market ibrexafungerp and any future product candidates we may seek to develop. We have only submitted one NDA and one supplemental NDA before, and we may be unable to do so for ibrexafungerp in additional indications or any future product candidate we may seek to develop. The conduct of successful Phase 2 and Phase 3 clinical trials is essential in obtaining regulatory approval, and the submission of a successful NDA is a complicated process. We have limited experience in preparing and submitting regulatory filings, have previously only sponsored four Phase 2 clinical trials and six Phase 3 clinical trials, and we have only submitted one NDA and one NDA Efficacy Supplement. Consequently, we may be unable to successfully and efficiently execute and complete our ongoing and planned clinical trials in a way that is acceptable to the FDA and leads to an approval of additional indications for ibrexafungerp or any future product candidate we may seek to develop. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we may seek to develop. In addition, failure to commence or complete, or delays in, our planned clinical trials would prevent us from or delay us in commercializing ibrexafungerp or any future product candidate we may develop. The environment in which our regulatory submissions may be reviewed changes over time, which may make it more difficult to obtain regulatory approval of any of our product candidates we may seek to develop or commercialize. The environment in which regulatory submissions are reviewed changes over time. For example, average review times at the FDA for NDAs have fluctuated over the last ten years, and we cannot predict the review time for any submission with any regulatory authorities. Review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes. Moreover, in light of widely publicized events concerning the safety risks of certain drug products, regulatory authorities, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk evaluation and mitigation strategies that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from preclinical studies and clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense, a delay or failure in obtaining approval or approval for a more limited indication or conditions of use than originally sought. In addition, data obtained from preclinical studies and clinical trials are subject to different interpretations, which could delay, limit or prevent regulatory review or approval of product candidates. Changes in FDA personnel responsible for review of our submissions could also impact the manner in which our data are viewed. Furthermore, regulatory attitudes towards the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including information on other products, policy changes and agency funding, staffing and leadership. We do not know whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. If BREXAFEMME, ibrexafungerp for other indications or any other future product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenue that is generated from their sales will be limited. The commercial success of BREXAFEMME, ibrexafungerp for other indications or any other product candidates we may seek to develop will depend upon the acceptance of these product candidates among physicians, patients, the medical community and healthcare payors. The degree of market acceptance of product candidates will depend on a number of factors, including: • limitations or warnings contained in the FDA- approved labeling; • changes in the standard of care for the targeted indications; • limitations in the approved indications; • availability of alternative therapies with potentially advantageous results, or other products with similar results at similar or lower cost, including generics and over-the-counter products; • lower demonstrated clinical safety or efficacy compared to other products; • occurrence of significant adverse side effects; • ineffective sales, marketing and distribution support; • lack of availability of coverage and adequate reimbursement from governmental health care programs, managed care plans and other third- party payors; • timing of market introduction and perceived effectiveness of competitive products; • lack of cost- effectiveness; • adverse publicity about our product candidates or favorable publicity about competitive products; • lack of convenience and ease of administration; and • potential product liability claims. If BREXAFEMME, or ibrexafungerp for other indications or any future product candidates we may seek to develop are approved, but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, sufficient revenue may not be generated from these product candidates, and we may not become or remain profitable. In addition, efforts to educate the medical community and third- party payors on the benefits of our product candidates may require significant resources and may never be successful. A significant use of antifungal drugs consists of treatment due to the presence of symptoms before diagnosis of the invasive fungal infections, and if recently approved diagnostic tools, or additional tools currently under development, for the quick diagnosis of invasive fungal infections are broadly used in the marketplace, the

number of treatments using antifungal drugs may decrease significantly, decreasing the potential market for ibrexafungerp. We believe that a large portion of the treatments using antifungal drugs are administered when symptoms of invasive fungal infections are present but a diagnosis of the infection has not yet been made, due to the rapid and potentially fatal progression of invasive fungal infections. Diagnostic tools recently approved by the FDA, or currently under development, for the rapid diagnosis of invasive fungal infections may significantly diminish the need to treat patients in advance of diagnosis of invasive fungal infections, which will reduce the potential market for ibrexafungerp. Moreover, if a rapid and accurate test of the susceptibility of a fungal infection to generically available treatments is developed and widely adopted, the market for ibrexafungerp may suffer. If resistance to ibrexafungerp develops quickly or cross-resistance with echinocandins becomes more common, our business will be harmed. We recognize that, over time, resistance develops against every antibacterial and antifungal drug. One or more strains of fungal pathogens may develop resistance to ibrexafungerp more rapidly than we currently expect, either because our hypothesis of the mechanism of action is incorrect or because a strain of fungi undergoes some unforeseen genetic mutation that permits it to survive. Since we expect lower resistance relative to other antifungal drug classes to be a major factor in the commercialization of ibrexafungerp, rapid development of such resistance or development of cross resistance with echinocandins would have a major adverse impact on the acceptability and sales of ibrexafungerp. Our approved product and product candidates may have undesirable side effects that may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market or otherwise limit their sales. It is impossible to predict when or if ibrexafungerp for indications other than VVC, RVVC or any other product candidate we may seek to develop will prove effective or safe, or whether we or GSK will receive marketing approval for ibrexafungerp for the treatment of indications other than VVC, RVVC, or whether we will receive marketing approval for any other products we may seek to develop. Unforeseen side effects from any product candidates could arise either during clinical development or, if approved, after the product has been marketed. The most commonly reported adverse events after oral administration of ibrexafungerp have been gastrointestinal (GI) events (i. e., nausea, diarrhea, vomiting). The gastrointestinal events reported have typically been transient (i. e., short duration), mild or moderate and not leading to discontinuation. The most commonly reported adverse events after IV administration of ibrexafungerp have been local reactions at the site of infusion. During our Phase 1 IV program in healthy volunteers, aimed to expand the safety margin that would allow greater flexibility of dosing options in patients, we observed three mild- to- moderate thrombotic events in healthy volunteers receiving the IV formulation of ibrexafungerp at the highest doses and highest concentrations. These events were reported to FDA as 15- day alert reports because they were unexpected and required anticoagulant therapy. The potential contribution of the IV formulation of ibrexafungerp to these events cannot be ruled out even though rates of thrombotic events due to intravenous catheters reported in the literature are comparable to those observed in the Phase 1 study. Serious adverse events (SAEs) are common when conducting clinical trials in a seriously ill population such as patients experiencing invasive candidiasis. Several SAEs have been reported in our clinical trials but only four of the events have been deemed by the investigator to be potentially related to ibrexafungerp, although other contributing factors could not be ruled out. These four serious adverse events include: one event of elevation of liver function tests in a subject who received a single dose of oral ibrexafungerp (resolved) and three events secondary to thrombi formation at site of IV infusion with the cyclodextrin- based IV formulation. Preclinical findings in the future could trigger the need to evaluate or monitor for specific potential safety concerns in clinical trials. The results of our clinical trials may show that ibrexafungerp and any future product candidates we may seek to develop cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, resulting in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or may lead us to abandon their development altogether. We or others may subsequently identify undesirable or unacceptable side effects caused by BREXAFEMME or any future product candidate we may seek to develop, in which case: • regulatory authorities may require the addition of labeling statements, specific warnings, precautions, contraindications or field alerts to physicians and pharmacies; • we or GSK may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; • there may be limitations on how the product can be promoted; • sales of the product may decrease significantly; • regulatory authorities may require us or GSK to take our approved product off the market; • we may be subject to litigation or product liability claims; and • our reputation may suffer. Any of these events could prevent us or our current or potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of products. We expect that BREXAFEMME, ibrexafungerp for the treatment of other indications, and any future product candidates we may seek to develop will face competition, and most of our competitors have significantly greater resources than we do. The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies. There are many foreign and domestic pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations actively engaged in research and development of products that may target the same markets as ibrexafungerp and any future product candidates we may seek to develop. We expect any products we develop to compete on the basis of, among other things, product efficacy, lack of significant adverse side effects and convenience and ease of treatment. For example, BREXAFEMME competes, and ibrexafungerp for other indications will compete, against current leading antifungal drugs, including voriconazole from the azole class, caspofungin from the echinocandin class, and liposomal amphotericin B from the polyenes class, many of which are currently available in generic form, or expected to be available in generic form at the time IV ibrexafungerp might be approved. Compared to us, many of our competitors in the antifungal market have, and potential competitors for any future product candidates we may seek to develop may have, substantially greater: • resources, including capital, personnel and technology; • research and development capability; • clinical trial expertise; • regulatory expertise; • intellectual property portfolios; • expertise in prosecution of intellectual property rights; • manufacturing and distribution expertise; and • sales and marketing expertise. As a result of these factors, our competitors and potential competitors may obtain

regulatory approval of their products more rapidly than we do. Our competitors and potential competitors may also develop drugs that are more effective, more widely used and less costly than ours and may also be more successful than us in manufacturing and marketing their products and maintaining compliance with ongoing regulatory requirements. Reimbursement decisions by third- party payors may have an adverse effect on pricing and market acceptance in the United States for BREXAFEMME, ibrexafungerp, and any future product candidates we may seek to develop. If there is not sufficient reimbursement for our products, it is less likely that our products will be purchased by patients and / or providers. Successful commercialization of pharmaceutical products usually depends on the availability of coverage and adequate reimbursement from third- party payors, including commercial insurers and federal and state healthcare programs. Patients and / or healthcare providers who purchase drugs generally rely on third- party payors to reimburse all or part of the costs associated with such products. As such, coverage and adequate reimbursement from third- party payors can be essential to new product acceptance and may have an effect on pricing. We do not know the extent to which BREXAFEMME will be able to obtain favorable coverage and adequate reimbursement from third- party payors. If we choose to bring other product candidates to market, they will be subject to similar uncertainty. We believe that ibrexafungerp and any other product candidates that are brought to market are less likely to be purchased by patients and / or providers if they are not adequately reimbursed by third- party payors. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third- party payors. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Furthermore, the market for our product candidates may depend on access to third- party payors' drug formularies, or lists of medications for which third- party payors provide coverage and reimbursement. Industry competition to be included in such formularies results in downward pricing pressures on pharmaceutical companies. Third- party payors may refuse to include a particular branded drug in their formularies when a competing generic product is available. The adoption of certain payment methodologies by third- party payors may limit our ability to profit from the sale of ibrexafungerp. For example, under Medicare, hospitals are reimbursed under an inpatient prospective payment system. This pricing methodology provides a single payment amount to hospitals based on a given diagnosis- related group. As a result, with respect to Medicare reimbursement for services in the hospital inpatient setting, hospitals could have a financial incentive to use the least expensive drugs for the treatment of invasive fungal infections, particularly the IV formulations of these drugs, as they are typically administered in the hospital, which may significantly impact our ability to charge a premium for ibrexafungerp. Coverage policies and third- party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for BREXAFEMME or other products for which the Company receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. All third- party payors, whether governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs, including mechanisms to encourage the use of generic drugs. Congress has also considered policies to lower the reimbursement formulas in federal and state healthcare programs. Furthermore, coverage of, and reimbursement for, drugs can differ significantly from payor to payor and may require significant time and resources to obtain. In addition, new laws or regulations could impact future coverage and reimbursement. Healthcare policy changes may have a material adverse effect on us. In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting healthcare industry, including reforms related to the payment for, the availability of and reimbursement for healthcare services in the United States, including pharmaceutical products. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under governmental funded programs, to minor modifications to existing programs. In March 2010, Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (~~or~~ the Affordable Care Act ). The Affordable Care Act is designed to expand access to affordable health insurance, control healthcare spending, and improve healthcare quality. The law included provisions to, among other things, tie Medicare provider reimbursement to healthcare quality and incentives, mandatory compliance programs, enhanced transparency disclosure requirements, increased funding and initiatives to address fraud and abuse, and incentives to state Medicaid programs to expand their coverage and services. It also imposed an annual tax on pharmaceutical manufacturers or importers who sell "branded prescription drugs." There have been **amendments to and** executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. **For example, the Tax Cuts and Jobs Act of 2017 included a provision repealing, effective January 1, 2019, the tax- based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On June 17, 2021 the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress.** On August 16, 2022, **President Biden signed** the Inflation Reduction Act of 2022 (~~or~~ IRA ~~)~~ **was signed** into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and creating a new manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the **Biden second Trump** Administration will impact the Affordable Care Act and our business. In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, including the Infrastructure Investment and Jobs Act, will stay in effect until 2032 unless additional Congressional action is taken. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional

inquiries, Presidential executive orders, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, the U. S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, the IRA, among other things (i) directs **the U. S. Department of Health and Human Services, (HHS),** to negotiate the price of certain high- expenditure, single- source drugs and biologics **that have been on the market for at least 7 years** covered under Medicare, **or the Medicare Drug Price Negotiation Program** and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29-15, 2023-2024, HHS announced the **list agreed- upon prices** of the first ten drugs that **were will be** subject to price negotiations, although the Medicare drug **Drug price-Price negotiation-Negotiation program Program** is currently subject to legal challenges. **It is unclear how the IRA On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject** be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration’s October 2022 executive order, on February 14, 2023, HHS released a report outlining three-- **the Medicare Drug Price Negotiation Program** new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. **It is unclear whether the models will be utilized in any health reform measures in the future.** Further, on December 7, 2023, ~~the Biden administration announced~~ an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act **was announced**. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework. **The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.** We cannot predict what healthcare reform initiatives may be adopted in the future, ~~particularly in light of the new presidential administration.~~ Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing, which could have a negative impact on our sales of any future approved products. We expect that a portion of the market for BREXAFEMME, ibrexafungerp for other indications, and any other product candidates we may seek to develop will be outside the United States. However, our product candidates may never receive approval or be commercialized outside of the United States. Before we or any commercial partners (including GSK) can market and commercialize any product candidates outside of the United States, there are numerous and varying regulatory requirements of other countries that will apply. Research and marketing authorization procedures vary among countries and can involve additional product testing and administrative review periods. The marketing authorization process in other countries may include all of the risks detailed above regarding failure to obtain FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country, or identification of potential safety concerns in one country, may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that: • ibrexafungerp and any future product candidates we may seek to develop may not generate preclinical or clinical data that are deemed sufficient by regulators in a given jurisdiction; • ibrexafungerp may not be approved for all indications requested, or any indications at all, in a given jurisdiction which could limit the uses of ibrexafungerp and any future product candidates we may seek to develop and have an adverse effect on product sales and potential royalties; and • such approval in a given jurisdiction may be subject to limitations on the indicated uses for which the product may be marketed or require costly post- marketing follow- up studies. Foreign countries may have requirements for marketing authorization holders or distributors to have a legal or physical presence in that country, and consideration of and compliance with these requirements may result in additional time and expense before we can pursue or obtain marketing authorization in foreign jurisdictions. If we do receive approval in other countries, we may enter into sales and marketing arrangements with third parties for international sales of any approved products. BREXAFEMME, ibrexafungerp, or any other future product candidates we may seek to develop, may still face future development and regulatory difficulties. For BREXAFEMME, ibrexafungerp, or any other future product candidates we may seek to develop, regulatory authorities may still impose significant restrictions on a product’s indicated uses or marketing or impose ongoing requirements for potentially costly post- approval studies. Given the number of high profile adverse events with certain drug products, regulatory authorities may require, as a condition of approval, costly risk evaluation and mitigation strategies, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, expedited reporting of certain adverse events, pre- approval of promotional materials and restrictions on direct- to- consumer advertising. For example, any labeling approved for any of our product candidates may include a restriction on the term of its use, or it may not include one or more intended indications. Furthermore, any new legislation addressing drug safety issues could result in delays or increased costs during the period of product development, clinical trials and regulatory

review and approval, as well as increased costs to assure compliance with any new post- approval regulatory requirements. Any of these restrictions or requirements could force us or our partners to conduct costly studies. BREXAFEMME, ibrexafungerp, and any other future product candidates we may seek to develop will also be subject to ongoing regulatory requirements for the packaging, storage, advertising, promotion, record- keeping and submission of safety and other post- market information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices (cGMP). As such, we and our contract manufacturers, which we will be responsible for overseeing and monitoring for compliance, are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. The FDA may hold us responsible for any deficiencies or noncompliance of our contract manufacturers in relation to ibrexafungerp and any other future product candidates we may seek to develop. Failure to follow cGMP can result in products being deemed adulterated, which carries significant legal implications. We will also be required to engage in pharmacovigilance activities and report certain adverse reactions and production problems, if any, to the FDA and to comply with certain requirements concerning advertising and promotion for products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved label. As such, we may not promote products for indications or uses for which they do not have approval. Failure to comply with FDA advertising and promotion standards, which are often subject to interpretation by regulators, may result in a wide range of exposure and liability for us. 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, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If the manufacturing or marketing of products fail to comply with applicable regulatory requirements, a regulatory agency may: • issue warning letters; • mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners; • require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance; • impose other civil or criminal penalties; • suspend regulatory approval; • suspend any ongoing clinical trials; • refuse to approve pending applications or supplements to approved applications filed by us, our partners or our potential future partners; • impose restrictions on operations, including costly new manufacturing requirements; or • seize or detain products or require a product recall. Non-compliance may also open a company to potential whistleblower lawsuits and the potential for liability under the False Claims Act. Pharmaceutical companies are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products. We are subject to regulation by other regional, national, state and local agencies, including the Department of Justice, the Office of Inspector General of the U. S. Department of Health and Human Services and other regulatory bodies. Violations of any of such laws and regulations could result in significant penalties being assessed against us. The federal Anti- Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. The Affordable Care Act, among other things, clarified that a person or entity need not have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it, in order to have committed a violation. In addition, the Affordable Care Act amended the federal civil False Claims Act to provide 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 federal civil False Claims Act. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. The federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties law, prohibit any person from, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under these laws for a variety of alleged marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company' s products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government healthcare programs. Companies have been prosecuted for causing false claims to be submitted because of the marketing of their products for unapproved uses and have also been prosecuted on other legal theories of Medicare and Medicaid fraud. The federal Health Insurance Portability and Accountability Act of 1996 (~~(-or-HIPAA -)~~) which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, regardless of the payor (e. g., public or private). Similar to the federal Anti- Kickback Statute, a person or entity need not have actual knowledge the statute or specific intent to violate it, in order to have committed a violation. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing regulations, which impose certain obligations with respect to safeguarding the privacy, security and transmission of individually identifiable health information on " covered entities, " such as certain healthcare providers, health plans, and healthcare clearinghouses and their respective " business associates, " as well as their covered subcontractors, that perform services for them, which involve

the creation, receipt, use, maintenance, transmission or disclosure of, individually identifiable health information for or on behalf of a covered entity. The Physician Payments Sunshine Act, created under the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The majority of states also have statutes or regulations similar to these laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Some of these states also prohibit certain marketing related activities including the provision of gifts, meals, or other items to certain health care providers. In addition, certain states, including California, Connecticut, Nevada, and Massachusetts, require pharmaceutical companies to implement compliance programs or marketing codes. Certain states also require pharmaceutical companies to file periodic reports with the state on sales, marketing, pricing, clinical trials and / or other activities, and / or register their sales and medical representatives. Compliance with various federal and state laws is difficult and time consuming, and companies that violate them may face substantial penalties. The potential sanctions include significant administrative, civil and criminal penalties, including monetary fines, exclusion from participation in federal health care programs, integrity oversight and reporting obligations to resolve allegations of non-compliance with these laws, disgorgement, criminal fines, imprisonment, contractual damage, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Because of the breadth of these laws and the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities or those of our commercial partners could be subject to challenge under one or more of these laws. Such a challenge could have a material adverse effect on our business and financial condition and growth prospects. We could become subject to government investigations and related subpoenas. Such subpoenas are often associated with previously filed qui tam actions, or lawsuits filed under seal under the federal civil False Claims Act. Qui tam actions are brought by private plaintiffs suing on behalf of the federal government for alleged federal civil False Claims Act violations. The time and expense associated with responding to such subpoenas, and any related qui tam or other actions may be extensive, and we cannot predict the results of our review of the responsive documents and underlying facts or the results of such actions. Responding to government investigations, defending any claims raised, and any resulting fines, restitution, damages and penalties, settlement payments or administrative actions, as well as any related actions brought by stockholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business. The number and complexity of both federal and state laws continues to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In particular, the Affordable Care Act includes a number of provisions aimed at strengthening the government's ability to pursue federal Anti-Kickback Statute and federal False Claims Act cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers, and amendments to the federal civil False Claims Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations. Responding to a government investigation or enforcement action would be expensive and time-consuming and could have a material adverse effect on our business and financial condition and growth prospects. If we fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our ability to commercialize our products and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Regulations, guidelines and recommendations published by various government agencies and organizations may affect the use of ibrexafungerp and any future product candidates we may seek to develop. Government agencies may issue regulations and guidelines directly applicable to us, our partners or our potential future partners and our product candidates. In addition, professional societies, practice management groups, private health / science foundations and organizations involved in various diseases from time to time publish guidelines or recommendations to the healthcare and patient communities. These various sorts of recommendations may relate to such matters as product usage, dosage, and route of administration and use of related or competing therapies. Changes to these recommendations or other guidelines advocating alternative therapies could result in decreased use of ibrexafungerp and any future product candidates we may seek to develop, which may adversely affect our results of operations. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating loss carryforwards in a taxable year is limited to 80 % of taxable income in such year. Portions of our state and federal net operating loss carryforwards began to expire in 2019. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the equity ownership of certain stockholders over a rolling three- year period), the corporation's ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes to offset its post- change income and taxes may be limited. We have determined that ownership changes have occurred and as a result, a portion of our NOL carryforwards are limited. We may also experience ownership changes in the future as a result of subsequent issuances of our common stock or other shifts in our stock ownership some of which may be outside of our control. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase

state taxes owed. As a result, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could adversely affect our future cash flows. Uncertainties in the interpretation and application of existing, new and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate. The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws, tax treaties or regulations proposed or implemented by the current or a future U. S. presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows. The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, the relative amounts of income before taxes in the various jurisdictions in which we operate, new or revised tax laws, or interpretations of tax laws and policies, the outcome of current and future tax audits, examinations or administrative appeals, our ability to realize our deferred tax assets, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. For tax years beginning after December 31, 2021, legislation commonly referred to as the “Tax Cuts and Jobs Act” requires taxpayers to capitalize and amortize certain research and development expenditures over five years if incurred in the United States and fifteen years if incurred in foreign jurisdictions, rather than deducting them currently. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified.

**Risks Related to Our Dependence on Third Parties** We are dependent on our license agreement with GSK to commercialize ibrexafungerp other than in the Greater China region and in the Russian Federation and certain other countries, and if GSK is not successful in commercializing ibrexafungerp in these areas, we will lose a significant source of potential revenue. Under the GSK License Agreement, GSK is to pay us milestone payments upon our achievement of specified regulatory, commercial and sales milestone events, as well as royalties on sales of ibrexafungerp in those countries in its territory. If GSK determines not to pursue commercialization of ibrexafungerp in those countries, we will not receive any commercial or sales milestone or royalty payments under the GSK License Agreement. We are dependent on our existing third-party collaboration with Hansoh to commercialize ibrexafungerp in the Greater China region, and if Hansoh is not successful in commercializing ibrexafungerp in these areas, we will lose a significant source of potential revenue. We currently have an exclusive license and collaboration agreement with Hansoh who will pay us milestone payments upon the achievement of specified development and commercial milestones. In addition, Hansoh will pay us royalties upon sales of ibrexafungerp by Hansoh. We are relying on Hansoh to commercialize ibrexafungerp in the Greater China area, including mainland China, Hong Kong, Macau, and Taiwan, and if Hansoh is not able to commercialize ibrexafungerp in those countries, or determines not to pursue commercialization of ibrexafungerp in those countries, we will not receive any milestone or royalty payments under the agreement. We are dependent on our existing third-party collaboration with R-Pharm to commercialize ibrexafungerp in the Russian Federation and certain other countries, and if R-Pharm is not successful in commercializing ibrexafungerp in those countries, we will lose a significant source of potential revenue. We currently have a development license and supply agreement with R-Pharm, a leading supplier of hospital drugs in Russia, pursuant to which we license to R-Pharm rights to develop and commercialize ibrexafungerp in the field of human health in Russia and certain smaller non-core markets. R-Pharm will pay us milestone payments upon the achievement of specified milestones, including registration of ibrexafungerp in a country and upon the achievement of specified levels of sales. In addition, R-Pharm will pay us royalties upon sales of ibrexafungerp by R-Pharm. We are relying on R-Pharm to commercialize ibrexafungerp in the countries covered by our agreement with it, and if R-Pharm is not able to commercialize ibrexafungerp in those countries, or determines not to pursue commercialization of ibrexafungerp in those countries, we will not receive any milestone or royalty payments under the agreement.

**Generally On February 24, 2022 worldwide economic conditions remain uncertain, particularly due to the effects of the war between Russia launched an invasion of Ukraine which has resulted and the conflicts in increased volatility the Middle East, disruptions in various the banking system and financial markets, and across increased inflation. The ongoing geopolitical conflicts in various parts of sectors. The U. S. and other the countries world, including but not limited to along with certain international organizations, have imposed economic sanctions on Russia and certain Russian individuals, Ukraine banking entities and corporations as a response to the Middle East invasion. The extent and duration of the military action, resulting sanctions and future market disruptions in the region are impossible difficult to predict. Moreover, the ongoing effects of the hostilities and sanctions may not be limited to Russia and Russian companies and may spill over to and negatively impact other regional and global economic markets of the world, including Europe and the U. S.** The ongoing military action along with the potential for a wider conflict could further increase financial market volatility and cause negative effects on regional and global economic markets, industries, and companies. It is not currently possible to determine the severity of any potential adverse impact of this event on our financial condition, or more broadly, upon the global economy. We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop and commercialize

product candidates. Developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products is expensive. Consequently, a portion of our strategy is to license to third parties rights to develop and commercialize product candidates, including candidates we have discovered other than ibrexafungerp, and if these third parties do not perform under our agreements with them, we will not receive any revenue from these collaborations. For example, we currently have a development license and supply agreement with R- Pharm, pursuant to which we license to R- Pharm rights to develop and commercialize ibrexafungerp in the field of human health in Russia and certain smaller non- core markets, and if ibrexafungerp receives marketing approval, we may enter into additional sales and marketing arrangements with third parties for international sales. If we are unable to enter into any of these arrangements on acceptable terms, or at all, we may be unable to market and sell ibrexafungerp and any future product candidates we may seek to develop in certain markets. We expect to face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of product candidates. When we partner with a third party for development and commercialization of a product candidate, we can expect to relinquish to the third party some or all of the control over the future success of that product candidate. Our collaboration partner may not devote sufficient resources to the commercialization of product candidates or may otherwise fail in their commercialization. The terms of any collaboration or other arrangement that we establish may not be favorable to us. In addition, any collaboration that we enter into may be unsuccessful in the development and commercialization of product candidates. In some cases, we may be responsible for continuing preclinical and initial clinical development of a partnered product candidate or research program, and the payment we receive from our collaboration partner may be insufficient to cover the cost of this development. If we are unable to reach agreements with suitable collaborators for product candidates, we could face increased costs, we may be forced to limit the number of product candidates we can commercially develop or the territories in which we commercialize them and we might fail to commercialize products or programs for which a suitable collaborator cannot be found. If we fail to achieve successful collaborations, our operating results and financial condition will be materially and adversely affected. We depend on third- party contractors for a substantial portion of our drug development activities and may not be able to control their work as effectively as if we performed these functions ourselves. We outsource, and intend to continue to outsource, substantial portions of our drug development activities to third- party service providers, including manufacturing and the conduct of our clinical trials and various preclinical studies. Our agreements with third- party service providers and CROs are and will be on a study- by- study basis and typically short- term. In all cases, we expect to be able to terminate the agreements with notice and be responsible for the supplier' s previously incurred costs. Because we rely on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. Even if we outsource activities, in most cases regulators will hold us responsible for the compliance of the activities performed, and hold us responsible for oversight and monitoring of the activities. In addition, the use of third- party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. There are a limited number of third- party service providers that have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third- party service providers can be difficult and time consuming and could cause delays in our development programs. We currently have a small number of employees devoted to clinical development activities, which limits the internal resources we have available to identify and monitor our third- party providers. To the extent we are unable to identify, retain and successfully manage the performance of third- party service providers in the future, our business may be adversely affected. As we do not intend to own or operate facilities for manufacturing, storage and distribution of drug substance or drug product we are and will be dependent on third parties for the manufacture of ibrexafungerp. If we experience problems with any of these third parties, the commercial manufacturing of ibrexafungerp could be delayed. The inability to manufacture sufficient commercial supplies of ibrexafungerp could adversely affect product commercialization. We do not currently have any agreements with third- party manufacturers for the long- term commercial supply of ibrexafungerp. We may encounter technical difficulties or delays in the transfer of ibrexafungerp manufacturing on a commercial scale to a third- party manufacturer, or may be unable to enter into agreements for commercial supply with third- party manufacturers, or may be unable to do so on acceptable terms. We may not be able to establish additional sources of supply for ibrexafungerp and any future product candidates we may seek to develop. These suppliers are subject to regulatory requirements covering manufacturing, testing, quality control and record keeping relating to product candidates and are also subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our product candidate supply while we seek to secure another supplier that meets all regulatory requirements. Reliance on third- party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including: • the possible breach of the manufacturing agreements or violation of regulatory standards by the third parties because of factors beyond our control; • the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities; and • the possibility of unforeseen natural disasters, public health crises, political crises and other catastrophic events or other events outside of our control impacting our third parties, such as COVID- 19 and its variants, which may cause delays in the ability of our suppliers to provide us with supplies on a timely basis. Any of these factors could result in delays or higher costs in connection with our clinical trials, regulatory submissions, required approvals or commercialization of ibrexafungerp and any future product candidates we may seek to develop. If we fail to establish or lose our relationships with CROs, our drug development efforts could be delayed. We are substantially dependent on third- party vendors and CROs for preclinical studies and clinical trials related to our drug discovery and development efforts. If we fail to establish or lose our relationship with any one or more of these providers, we could experience a significant delay in both

identifying another comparable provider and then contracting for its services, which could adversely affect our development efforts. We may be unable to retain an alternative provider on reasonable terms, or at all. Even if we locate an alternative provider, it is likely that this provider will need additional time to respond to our needs and may not provide the same type or level of services as the original provider. In addition, any contract research organization that we retain will be subject to the FDA's regulatory requirements and similar foreign standards and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of ibrexafungerp and any future product candidates we may seek to develop could be delayed, which could severely harm our business and financial condition.

**Risks Relating to Our Intellectual Property** We were dependent on Merck for the establishment of our intellectual property rights related to ibrexafungerp, and if Merck did not establish our intellectual property rights with sufficient scope to protect ibrexafungerp, we may have limited or no ability to assert intellectual property rights to ibrexafungerp. Under our agreement with Merck, Merck was responsible for establishing the intellectual property rights to ibrexafungerp. As we were not responsible for the establishment of our intellectual property rights to ibrexafungerp, we have less visibility into the strength of our intellectual property rights to ibrexafungerp than if we had been responsible for the establishment of these rights. If Merck did not establish those rights such that they are of sufficient scope to protect ibrexafungerp, then we may not be able to prevent others from using or commercializing ibrexafungerp, and others may be able to assert intellectual property rights in ibrexafungerp and prevent us from further pursuing the development and commercialization of ibrexafungerp. Further, GSK has prosecution and enforcement rights for this IP and, if GSK does not determine to pursue prosecution and enforcement of intellectual property, the value of this intellectual property may diminish or be lost. It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of ibrexafungerp and any future product candidates we may seek to develop and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing ibrexafungerp and any future product candidates we may seek to develop is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No absolute policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. Changes in either the patent laws or in interpretations of patent laws in the United States and foreign jurisdictions may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that we currently own or that may be issued from the applications we have filed or may file in the future or that we have licensed or may license from third parties, including Merck for ibrexafungerp. Further, if any patents we obtain or license are deemed invalid or unenforceable, it could impact our ability to commercialize or license our technology. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are similar to ibrexafungerp and any future product candidates we may seek to develop but that are not covered by the claims of our patents;
- if we encounter delays in our clinical trials, the period of time during which we could market our drug candidates under patent protection would be reduced;
- we might not have been the first to conceive, make or disclose the inventions covered by our patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- any patents that we obtain may be invalid or unenforceable or otherwise may not provide us with any competitive advantages; or
- the patents of others may have a material adverse effect on our business.

Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of the product candidates that may be disclosed or methods involving these candidates that may be disclosed in the parent patent application. We plan to pursue divisional patent applications and / or continuation patent applications in the United States and many other countries to obtain claim coverage for inventions that were disclosed but not claimed in the parent patent application, but may not succeed in these efforts. Composition of matter patents on the active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents generally provide protection without regard to any method of use. We cannot be certain that the claims in our patent applications covering composition-of-matter of our drug candidates will be considered patentable by the U. S. Patent and Trademark Office (USPTO) courts in the United States or by the patent offices and courts in foreign countries. Method of use patents protect the use of a product for the method recited in the claims. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to or induce the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation, interference, or derivation proceedings may fail, resulting in harm to our business, and, even if successful, may result in substantial costs and distract our management and other employees. We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, licensees, licensors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information such that our competitors may obtain it. Enforcing a claim that a third party illegally obtained and is using any of

our trade secrets is expensive and time consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how, such as new therapies, including therapies for the indications we are targeting. If others seek to develop similar therapies, their research and development efforts may inhibit our ability to conduct research in certain areas and to expand our intellectual property portfolio, and also have a material adverse effect on our business. We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to enforce or protect our rights to, or use, our technology. If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced. These lawsuits are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents or sustaining their validity and enforceability. In addition, there is a risk that the court will decide that such patents are not valid or that we do not have the right to enforce them. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the grounds that such other party's activities do not infringe such patents. In addition, the United States Court of Appeals for the Federal Circuit and the Supreme Court of the United States continue to address issues under the United States patent laws, and the decisions of those and other courts could adversely affect our ability to sustain the validity of our issued or licensed patents and obtain new patents. Furthermore, a third party may claim that we or our manufacturing or commercialization partners or customers are using inventions covered by the third party's patent rights and may go to court to stop us or our partners and / or customers from engaging in our operations and activities, including making or selling ibrexafungerp and any future product candidates we may seek to develop. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. There is a risk that a court would decide that we or our commercialization partners or customers are infringing the third party's patents and would order us or our partners or customers to stop the activities covered by the patents. In that event, we or our commercialization partners or customers may not have a viable way around the patent and may need to halt commercialization or use of the relevant product. In addition, there is a risk that a court will order us or our partners or customers to pay the other party damages for having violated the other party's patents or obtain one or more licenses from third parties, which may be impossible or require substantial time and expense. We cannot predict whether any license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our drug candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In such events, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. In the future, we may agree to indemnify our commercial partners and / or customers against certain intellectual property infringement claims brought by third parties which could increase our financial expense, increase our involvement in litigation and / or otherwise materially adversely affect our business. Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation, which could adversely affect our intellectual property rights and our business. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, because searches and examinations of patent applications by the USPTO and other patent offices may not be comprehensive, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our patents or pending applications. Our competitors may have filed, and may in the future file, patent applications and may have obtained patents covering technology similar to ours. Any such patents or patent application may have priority over our patent applications, which could further require us to obtain or license rights to issued patents covering such technologies. If another party has obtained a U. S. patent or filed a U. S. patent application on inventions similar to ours, we may have to participate in a proceeding before the USPTO or in the courts to determine which patent or application has priority. The costs of these proceedings could be substantial, and it is possible that our application or patent could be determined not to have priority, which could adversely affect our intellectual property rights and business. We have received confidential and proprietary information from collaborators, prospective licensees and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have improperly used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If we are not successful, our ability to continue our operations and our business could be materially, adversely affected. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our

operations, on our ability to hire or retain employees, or otherwise on our business. Risks Related to Employee Matters and Managing Growth We may not be able to manage our business effectively if we are unable to attract and retain key personnel. We may not be able to attract or retain qualified management, finance, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Stock- based awards are critical to our ability to recruit, retain and motivate highly skilled talent. However, the trading price of our common stock as listed on the Nasdaq Global Market has traded at or below the exercise price of a significant portion of the stock options currently held by our executive officers and key employees. This may reduce the retention value of these options and we may need to grant additional stock options, make further amendments to the terms of existing option awards, or provide alternative compensation and retention programs to continue to retain our employees, especially our key employees and executive officers. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. If we are unable to retain our current executive officers and key employees our ability to implement our business strategy successfully could be seriously harmed. We may need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth. As of March 1, 2024-2025, we had 29-28 full time employees. Further, as we advance ibrexafungerp and SCY- 247 through ~~preclinical~~ clinical studies, clinical trials and commercialization for other indications, we will need to increase our product development, scientific, marketing, sales and administrative headcount to manage these efforts. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees with the expertise and experience we will require;
- manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites;
- develop a marketing and sales infrastructure; and
- continue to develop our operational, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth, our business may be adversely affected. Other Risks Relating to Our Business We may face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization. The use of product candidates in clinical trials and the sale of any products for which we may obtain marketing approval expose us to the risk of product liability claims. Product liability claims may be brought against us or our partners by participants enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling products. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- decreased demand for product candidates and loss of revenue;
- impairment of our business reputation;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize product candidates.

We have obtained limited product liability insurance coverage for our clinical trials domestically and in selected foreign countries where we are conducting clinical trials as required by local country regulations, in addition to limited product liability coverage for BREXAFEMME. Our ~~coverage~~ annual limit is currently limited to \$ 25. 0 million per occurrence and \$ 25. 0 million in the aggregate per year. As such, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to product liability. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for product candidates, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash available to develop ibrexafungerp and any future product candidates we may seek to develop and adversely affect our business. Our internal computer systems, or those used by our contract research organizations or other contractors or consultants, may fail or suffer security breaches. 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, data leakage and security breaches from computer viruses, unauthorized access, social engineering, the acts or omissions of our workforce or others with authorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of the occurrence of any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our or other contractors or consultants' operations, it could result in a material disruption of our product candidate development programs. For example, the loss of clinical study data from completed or ongoing clinical studies for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of any product candidates could be delayed. Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities. We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, auto, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations. Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing. Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have

attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive. We are subject to stringent and evolving U. S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences. In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share confidential, proprietary, and sensitive information, including personal data, business data, trade secrets, intellectual property, information we collect about trial participants in connection with clinical trials, sensitive third- party data, business plans, transactions, and financial information. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. In the U. S., federal, state, and local governments have enacted numerous data privacy and security laws and regulations, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws). For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, impose certain obligations with respect to safeguarding the privacy, security and transmission of individually identifiable health information on “ covered entities, ” such as certain healthcare providers, health plans, and healthcare clearinghouses and their respective “ business associates ” that perform services for them. In addition, in the past few years, numerous U. S. states — including California, Virginia, Colorado, Connecticut, and Utah — have enacted comprehensive data privacy and security laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 (CCPA), as amended by the California Privacy Rights Act of 2020, applies to personal data of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties for violations of up to \$ 7, 500 per violation, as well as a private right of action for individuals impacted by certain data breaches. The CCPA and other comprehensive state data privacy and security laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Outside the U. S., an increasing number of laws, regulations, and industry standards may govern data privacy and security, including information that we collect about patients in connection with clinical trials and our other operations abroad. For example, the EU’ s General Data Protection Regulation (EU GDPR) and the United Kingdom’ s GDPR (UK GDPR) impose strict requirements for processing personal data, including health- related information. For example, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to the greater of 20 million euros or 4 % of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross- border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose data privacy and security laws they believe are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK’ s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the EU GDPR’ s cross- border data transfer limitations. In addition to data privacy and security laws, we are or may become contractually subject to industry standards adopted by industry groups and

may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences. Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and / or oversight; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences. In the ordinary course of our business, we and the third parties upon which we rely process confidential, proprietary, and sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our confidential, proprietary, and sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services. We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of confidential, proprietary, and sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process confidential, proprietary, and sensitive data in a variety of contexts, including, without limitation, CROs, CMOs, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third-party service providers to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties’ information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties’ infrastructure in our supply chain or our third-party partners’ supply chains have not been compromised. Any of the previously identified or similar threats could

cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our confidential, proprietary, and sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services. We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry- standard or reasonable security measures to protect our information technology systems and confidential, proprietary, and sensitive data. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities, in our information systems (such as our hardware and / or software, including that of third parties upon which we rely). We may not detect and remediate all such vulnerabilities including in a timely manner. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident. Applicable data privacy and security obligations may require us to notify relevant stakeholders, such as governmental authorities, partners, and affected individuals, of security incidents. Such disclosures may involve inconsistent requirements and are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing confidential, proprietary, and sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management' s attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

**Risks Relating to Owning Our Common Stock** The market price of our common stock may be highly volatile. The trading price of our common stock may be volatile. The following factors, in addition to other factors described in this “ Risk Factors ” section and elsewhere in this report, may have a significant impact on the market price of our common stock:

- the level of sales of BREXAFEMME;
- the results of our preclinical testing or clinical trials;
- the ability to obtain additional funding;
- any delay in submitting an NDA or similar foreign applications for ibrexafungerp for the treatment of indications other than VVC, RVVC, and any future product candidate we may seek to develop or any adverse development or perceived adverse development with respect to the FDA' s review of that NDA or a foreign regulator' s review of a similar applications;
- maintenance of our existing collaborations or ability to enter into new collaborations;
- our collaboration partners' election to develop or commercialize product candidates under our collaboration agreements or the termination of any programs under our collaboration agreements;
- any intellectual property infringement actions in which we or our licensors and collaboration partners may become involved;
- our ability to successfully develop and commercialize future product candidates;
- changes in laws or regulations applicable to future products;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- achievement of financial projections we may provide to the public;
- achievement of the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- changes in the structure of healthcare payment systems;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- legislation or regulation that mandates or encourages the use of generic products;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- general economic and market conditions and overall fluctuations in the U. S. equity markets;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future; and
- trading volume of our common stock.

In addition, companies trading in the stock market in general, and the Nasdaq Global Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Future sales and issuances of our common stock or rights to purchase common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales may also result in new investors gaining rights superior to our existing stockholders. For example, **on November 15, 2019, we issued and sold \$ 16 million of 6.0% convertible senior notes. The holders may convert their convertible notes at their option at any time prior to the close of business on the business day immediately preceding March 15, 2025-2024, we entered into**. Upon conversion of the convertible notes by a holder, **Controlled Equity OfferingSM Sales Agreement** (the holder will receive **Sales Agreement**)

with Cantor Fitzgerald & Co., as sales agent, pursuant to which we may issue and sell shares of our common stock for, together, if applicable, with cash in lieu of any ~~an fractional share aggregate maximum offering price of \$ 50. 0 million~~ Holders who convert may also be entitled to receive, under certain circumstances, an interest make ~~“ at - whole payment payable in the market ” offering program under which we have sold zero~~ shares of ~~our~~ common stock ~~as of December 31, 2024~~. In addition, ~~as opportunities present themselves following certain corporate events that occur prior to the maturity date~~, we ~~may enter into financing~~ will, in certain circumstances, increase the conversion rate for ~~or similar arrangements a~~ holder who elects to convert its convertible notes in connection with such a corporate event. To the extent holders of these ~~the future~~ notes convert the notes, ~~including the issuance of debt securities our~~ ~~or equity~~ stockholders may experience substantial dilution. Additionally, the holders of our outstanding warrants also may exercise their right to buy our common stock ~~which could result in additional dilution to our stockholders~~. Anti- takeover provisions in our 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 and our bylaws may delay or prevent an acquisition of us, including the ability of our board of directors to establish new series of preferred stock and issue shares of these new series, which could be used by our board of directors to oppose a hostile takeover attempt, which some stockholders may believe would be in the best interests of stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management, including the elimination of cumulative voting, inability of our stockholders to call special meetings or take action by written consent, ability of our board of directors to fill board vacancies, and ability of our board of directors to determine the size of the board of directors. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits stockholders owning in excess of 15 % of our outstanding voting stock from merging or combining with us. Finally, our charter documents establish advance notice requirements for nominations for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings. Although we believe these provisions together provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. ~~Our business could be adversely affected by the continuation of the exposure to COVID-19, in regions where we or third parties on which we rely have significant concentrations of clinical trial sites, manufacturing facilities, or other business operations. Our business could be adversely affected by the continuation of the exposure to COVID-19, in regions where we or third parties on which we rely have significant concentrations of clinical trial sites, manufacturing facilities, or other business operations. We have a significant number of clinical trial sites in countries that have been directly affected by COVID-19, and depend on manufacturing operations for various stages of our supply chain in countries affected by COVID-19. The ultimate impact of COVID-19 is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our activities dependent on regulatory authorities, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.~~