UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-36365

SCYNEXIS, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**56-2181648**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1 Evertrust Plaza, 13th Floor Jersey City, NJ	**07302 - 6548**
(Address of principal executive offices)	**(Zip Code)**

(201) 884-5485
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	SCYX	Nasdaq Global Market

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of its Common Stock on the Nasdaq Global Market on June 30, 2022 was $60,150,447. Excludes 257,453 shares of the registrant's Common Stock held by executive officers and directors outstanding at June 30, 2022. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of March 1, 2023, there were 33,324,131 shares of the registrant's Common Stock outstanding.

Documents Incorporated by Reference

Portions of the registrant's proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2023 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2022.

SCYNEXIS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2022

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "expectations," "plan," "anticipate," "believe," "estimate," "project," "predict," "potential" and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading "Risk Factors." Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by our cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

RISK FACTOR SUMMARY

Risks and uncertainties we face are set forth in this Annual Report on Form 10-K in greater detail under the heading "Risk Factors." The following is a summary of these risk factors:

Risks Relating to Our Financial Condition and Need for Additional Capital

- We have entered into a License Agreement with GSK, which is subject to closing conditions, including expiration or termination of the HSR waiting period, and if we are not able to close the transaction contemplated by the License Agreement we will not be able to receive the benefits expected from the License Agreement, which would materially and adversely affect our prospects for generating revenue from BREXAFEMME and ibrexafungerp.
- We have never been profitable, we have only one product approved for commercial sale, and to date we have generated limited revenue from product sales. As a result, our ability to curtail our losses and reach profitability is unproven, and we may never achieve or sustain profitability.
- 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 programs for ibrexafungerp;
- Our operating activities may be restricted as a result of covenants related to the indebtedness under our senior convertible notes and our loan payable. 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, statement of operation, and our balance sheet; and
- Unfavorable U.S. and global economic conditions could adversely affect our ability to access capital.

Risks Relating to the Development, Regulatory Approval and Commercialization of Our Product Candidates For Human Use

- We cannot be certain that certain indications for ibrexafungerp will receive regulatory approval in the indications we are pursuing, and without regulatory approval, we will not be able 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 U.S. Food and Drug Administration (FDA) for the indications we are pursuing.

- 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.
- 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.
- We have only submitted one 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.
- If BREXAFEMME 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.
- If resistance to ibrexafungerp develops quickly or cross-resistance with echinocandins becomes more common, our business will be harmed.
- If we are unable to obtain regulatory approval of both the oral and IV formulations of ibrexafungerp, ibrexafungerp may not achieve broad market acceptance and sales will be limited.
- Our 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.
- We have one marketed drug, BREXAFEMME for the treatment of VVC and RVVC, and if we are unable to close the License Agreement with GSK or enter into an acceptable licensing arrangement with another company, we may not be able to successfully continue to commercialize BREXAFEMME for these indications.
- If we are unable to establish an effective marketing infrastructure, we may not be able to successfully commercialize ibrexafungerp and any future product candidates we may seek to develop.
- We expect that BREXAFEMME 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.
- 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.

Risks Related to Our Dependence on Third Parties

- We are dependent on our existing third-party collaborations for drug development and to commercialize ibrexafungerp, and if these third-parties do not perform well under these collaborations, or our prospects may be harmed.
- As we do not intend to own or operate facilities for manufacturing, storage and distribution of drug substance or drug product, we are 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.

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.
- It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.
- 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.

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 need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.

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.
- Our internal computer systems, or those used by our contract research organizations or other contractors or consultants, may fail or suffer security breaches.
- Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.
- Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.
- 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.
- Our business may 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.

ITEM 1. BUSINESS

Overview

SCYNEXIS, Inc. is pioneering innovative medicines to potentially help millions of patients worldwide in need of new options to overcome and prevent difficult-to-treat and drug-resistant infections. We are developing our lead product candidate, ibrexafungerp, as a broad-spectrum, intravenous (IV)/oral agent for multiple fungal indications in both the community and hospital settings. In June 2021 and December 2022, we announced that the FDA approved BREXAFEMME (ibrexafungerp tablets) for treatment of patients with vulvovaginal candidiasis (VVC), also known as vaginal yeast infection, and for the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC), respectively. In October 2022, we announced that we were actively pursuing a U.S. commercialization partner to out-license BREXAFEMME in order to refocus our resources on the further clinical development of ibrexafungerp for severe, hospital-based indications, while keeping BREXAFEMME on the market and available to patients, and have ceased actively promoting BREXAFEMME.

On March 30, 2023, we entered into a license agreement (the License Agreement) with GlaxoSmithKline Intellectual Property (No. 3) Limited (GSK). Pursuant to the terms of the License Agreement, we granted GSK an exclusive (even as to us and our affiliates), royalty-bearing, sublicensable license for the development, manufacture, and commercialization of ibrexafungerp, including the approved product BREXAFEMME, for all indications, in all countries other than Greater China and certain other countries already licensed to third parties (the GSK Territory). If the existing licenses granted to or agreements with third parties are terminated with respect to any country, GSK will have an exclusive first right to negotiate with us to add those additional countries to the GSK Territory. We retain rights to all other assets, with GSK receiving a right of first negotiation (ROFN) to any other enfumafungin-derived compounds or products that we may control. Under the terms of the License Agreement, we are responsible for the execution and costs of the on-going clinical studies of ibrexafungerp for multiple indications, including the treatment of life-threatening invasive fungal infections caused primarily by *Candida* spp. (including *C. auris*) and *Aspergillus* spp. in hospitalized patients, and we have the potential to receive success-based milestones to offset those costs. The consummation of the transactions under the License Agreement is subject to the satisfaction of customary closing conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the HSR Act); provided, that either we or GSK may terminate the License Agreement if expiration or termination of the applicable waiting period under the HSR Act has not occurred within nine months of the signing of the License Agreement. The parties expect the transactions contemplated by the License Agreement to close in the second quarter of 2023 (such closing, the GSK Closing).

Under the terms of the License Agreement, we will receive an upfront payment of $90 million. We are also eligible to receive potential:

- regulatory approval milestone payments of up to $70 million;

- commercial milestone payments of up to $115 million based on first commercial sale in invasive candidiasis (U.S./EU);
- and sales milestone payments of up to $242.5 million based on annual net sales, with a total of $77.5 million to be paid upon achievement of multiple thresholds up through $200 million; a total of $65 million to be paid upon achievement of multiple thresholds between $300 million and $500 million; and $50 million to be paid at each threshold of $750 million and $1 billion.

We will be responsible for the execution and costs of the ongoing clinical studies of ibrexafungerp but will have the potential to receive up to $75.5 million in success-based development milestones, which are comprised of up to $65 million for the achievement of three interim milestones associated with our continued performance of the ongoing MARIO Study and $10.5 million for the successful completion of the MARIO Study. See further details of the License Agreement as described in "Collaborations and Licensing Agreements Associated with Our Core Drug Development Operations - GSK" below.

We, Hercules Capital, Inc. (Hercules Capital) and Silicon Valley Bridge Bank, N.A. (SVB) are party to a Loan and Security Agreement dated as of May 13, 2021 (the Loan Agreement), pursuant to which Hercules Capital, SVB and each of the other lenders from time-to-time party to the Loan and Security Agreement (collectively, the Lenders) loaned to us $35 million. In connection with the entering into of the License Agreement, we entered into a First Amendment and Consent to Loan and Security Agreement with the Lenders pursuant to which the Lenders consented to us entering into the License Agreement and we agreed to pay to the Lenders an amount equal to the sum of (i) all outstanding principal plus all accrued and unpaid interest with respect to the amounts loaned under the Loan Agreement (approximately $35.4 million), (ii) the prepayment fee payable under Loan Agreement ($262,500), (iii) the final payment payable under Loan Agreement ($1,382,500), and (iv) all other sums, if any, that shall have become due and payable with respect to loan advances under the Loan Agreement. These payments by us will become due upon the earliest of (A) one business day following receipt by us of the $90 million upfront payment payable to us under the License Agreement, (B) June 1, 2023, or (C) the termination of the License Agreement.

Ibrexafungerp, the first representative of a novel class of antifungal agents called triterpenoids, is a structurally distinct glucan synthase inhibitor and has shown *in vitro* and *in vivo* activity against a broad range of human fungal pathogens such as *Candida* and *Aspergillus* genera, including multidrug-resistant strains, as well as *Pneumocystis, Coccidioides, Histoplasma* and *Blastomyces* genera. *Candida* and *Aspergillus* genera are the fungi responsible for approximately 85% of all invasive fungal infections in the United States (U.S.) and Europe. To date, we have characterized the antifungal activity, pharmacokinetics, and safety profile of the oral and IV formulations of ibrexafungerp in multiple *in vitro*, *in vivo*, and clinical studies. The FDA has granted Qualified Infectious Disease Product (QIDP) and Fast Track designations to ibrexafungerp for the indications of VVC (including the prevention of recurrent VVC), invasive candidiasis (IC) (including candidemia), and invasive aspergillosis (IA), and has granted Orphan Drug designations for the IC and IA indications. The European Medicines Agency has granted Orphan Medicinal Product designation to ibrexafungerp for IC and the Medicines and Healthcare Regulatory Agency has granted ibrexafungerp the Innovation Passport designation for the treatment of IC. These designations may provide us (or GSK following the GSK Closing) with additional market exclusivity and/or expedited regulatory paths.

BREXAFEMME

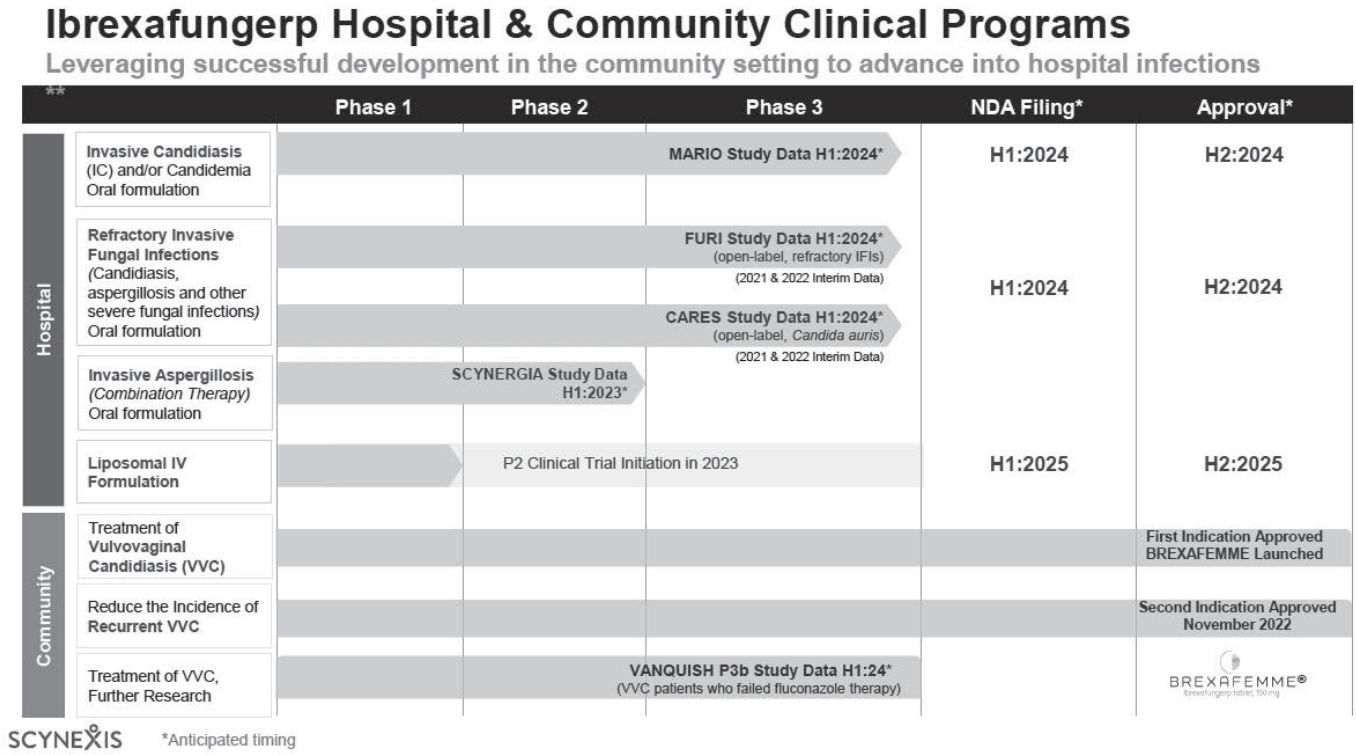
In June 2021, the FDA approved BREXAFEMME for use in patients with VVC. This approval was based on positive results from two Phase 3, randomized, double-blind, placebo-controlled, multi-center studies (VANISH-303 and VANISH-306), in which oral ibrexafungerp demonstrated statistically superior efficacy compared to placebo and a favorable tolerability profile in women with VVC. The FDA granted BREXAFEMME five years of exclusivity extension under the Generating Antibiotic Incentives Now (GAIN) Act, which is added to five years of new chemical entity (NCE) exclusivity, for a combined ten-year period of regulatory exclusivity. BREXAFEMME also is protected by multiple patents, including a composition-of-matter patent covering the ibrexafungerp molecule. With patent term extension, this patent is expected to expire in 2035, providing an expected 13 years of protection from generic competitors in the U.S. In December 2022, we announced that the FDA approved a second indication for BREXAFEMME for the reduction in the incidence of RVVC. This approval was based on positive results from the pivotal Phase 3 CANDLE study that evaluated the safety and efficacy of monthly dosing of ibrexafungerp to reduce the incidence of RVVC.

In October 2022, we announced that we were actively pursuing a U.S. commercialization partner to out-license BREXAFEMME in order to refocus our resources on the further clinical development of ibrexafungerp for severe, hospital-based indications, while keeping BREXAFEMME on the market and available to patients, and have ceased actively promoting BREXAFEMME. As a result, we wound down our promotional activities associated with BREXAFEMME and we concluded the partnership with our contracted commercial sales partner, Amplity Health (Amplity), on November 30, 2022. On March 30, 2023, we entered into the License Agreement with GSK. Pursuant to the terms of the License Agreement, we granted GSK an exclusive (even as to us and our affiliates), royalty-bearing, sublicensable license for the development, manufacture, and commercialization of ibrexafungerp, including the approved product BREXAFEMME, for all indications, in the GSK Territory.

Our Platform of Indications

Ibrexafungerp Hospital and Community Clinical Programs

We continue to actively advance our clinical programs, leveraging the potential of ibrexafungerp to be a suitable treatment for multiple indications with significant unmet medical needs and considerable commercial opportunities. The following illustration summarizes the status of the indications for ibrexafungerp currently being pursued in the hospital and community settings, as well as our current expectations regarding the time of reporting data and, if the data supports it, the potential filing of an NDA and FDA approval (or, following the GSK Closing, if consistent with GSK's strategy, the potential filing of an NDA by GSK and, if GSK submits an NDA at such time, the potential FDA approval):



Invasive Candidiasis and/or Candidemia

Enrollment is continuing in our prospective, randomized, double-blind, global Phase 3 study to evaluate the efficacy, safety and tolerability of oral ibrexafungerp as a step-down therapy for patients with IC including candidemia following IV echinocandin therapy in the hospital compared to currently available therapies (the MARIO study). Eligible patients with IC will receive treatment with IV echinocandin and will then be switched to either oral ibrexafungerp or a standard of care option, either oral fluconazole or best available therapy (BAT) for subjects with infections caused by fluconazole non-susceptible strains, once step-down criteria are met. Approximately 220 patients will be enrolled and randomized in the study, and we expect topline results in the first half of 2024 and a potential approval by the end of 2024.

The primary objective of the study is to determine whether treatment of IC with IV echinocandins followed by oral ibrexafungerp is as effective as treatment with IV echinocandins followed by oral fluconazole (or BAT), the current standard of care. The primary end point of the study will be all-cause mortality at 30 days after initiation of antifungal therapy.

Refractory Invasive Fungal Infections (rIFI)

We achieved a target enrollment of 200 patients in our Phase 3 FURI study as well as the target enrollment of 30 patients in our Phase 3 CARES study. We anticipate study completion activities for both studies in the first half of 2023 follow by a Data Review Committee review and topline data in the first half of 2024. The data from the MARIO study along with data from FURI and CARES studies are intended to be supportive of an NDA submission in 2024 with an anticipated first approval for an indication in the hospital setting later in 2024.

The FURI study is evaluating oral ibrexafungerp as a salvage treatment in patients with a variety of difficult-to-treat mucocutaneous and invasive fungal infections that are refractory to or intolerant of current standards of care, or require a non-azole oral step-down therapy for treatment of azole-resistant species. The CARES study is focused on hospitalized patients with invasive candidiasis caused by the multidrug-resistant *Candida auris* organism, which is associated with high mortality, and the

interim analysis was the first clinical trial data of an investigational treatment against infections caused by *Candida auris*. *Candida auris* has been recently declared an "Urgent Threat" to public health by the Centers for Disease Control and Prevention (CDC) in its report, Antibiotic Resistance Threats in the United States, 2019, as it can be multidrug-resistant, has resulted in high mortality rates (up to 60%), and can be spread from patients (and surfaces) to patients, resulting in hospital outbreaks. The CARES study is intended to provide rapid access to oral ibrexafungerp for patients suffering from this life-threatening infection.

The open-label designs of the FURI and CARES studies permit evaluation of the data on an interim basis to further inform subsequent regulatory steps of the development program. We believe that compelling data from the FURI and/or CARES studies could allow ibrexafungerp to become eligible for the regulatory LPAD, potentially enabling an NDA submission (which would be by GSK following the GSK Closing) based on streamlined development. The LPAD was established under the 21st Century Cures Act of 2016, and FDA draft guidance issued in June 2019 suggests smaller, shorter or fewer clinical trials may be appropriate to support approval to treat a serious or life-threatening infection in a limited population with unmet needs. Positive clinical findings from these the FURI and CARES studies have so far reinforced the potential role of oral ibrexafungerp as a novel therapy to combat severe and difficult-to-treat fungal infections, including multidrug-resistant *Candida auris*.

Invasive Aspergillosis

Based on promising pre-clinical data from combination use of ibrexafungerp with voriconazole, the current standard of care, vs. *Aspergillus* spp., we are conducting a Phase 2 study (SCYNERGIA study) of oral ibrexafungerp in combination with voriconazole in patients with IA. This study is a randomized, double-blind trial with the objective of assessing the safety and efficacy of oral ibrexafungerp in combination with voriconazole, compared to voriconazole alone. We believe that ibrexafungerp's broad activity against *Aspergillus* spp., including azole-resistant strains, along with its minimal drug-drug interactions, high tissue penetration into the lungs, and oral formulation allowing for long-term administration, may make it an ideal candidate for use as combination therapy to provide improved outcomes vs. standard of care.

We have completed the enrollment of SCYNERGIA, although the number of patients is smaller than initially projected. The prioritization of hospital resources toward addressing COVID-19 has impacted the ability of many institutions to focus on screening and enrolling patients into some clinical trials, including SCYNERGIA. We expect to provide topline data for SCYNERGIA in the first half of 2023.

IV Ibrexafungerp Development Program

We have completed a Phase 1 randomized, double-blind, placebo-controlled single and multiple ascending dose study evaluating the safety, tolerability, and pharmacokinetics of the liposomal IV formulation of ibrexafungerp in 64 healthy subjects with treatment durations of up to seven days. The liposomal IV formulation of ibrexafungerp was designed to optimize tolerability and address dose-limiting infusion site irritation adverse events observed with previous formulations. The study was conducted in South Africa and dosing began in March 2021 and the last cohort was completed in October 2021. The liposomal IV formulation of ibrexafungerp was generally well tolerated with no serious adverse events reported. The most common adverse events were mostly mild (a few moderate) reactions at the infusion site. The dosing was successfully progressed until the target exposure was achieved (i.e., exposure associated with efficacy from animal models). Should the GSK Closing not occur, we are planning to begin a Phase 2 study of the liposomal IV formulation in 2023.

Treatment of VVC

In the second quarter of 2022, enrollment began in a new Phase 3b, open-label, multicenter study (VANQUISH) to evaluate the efficacy, safety and tolerability of oral ibrexafungerp as a treatment for complicated VVC in patients who have failed treatment with fluconazole, based on mycological and clinical outcomes. The VANQUISH study will enroll approximately 150 complicated VVC patients who will receive 600 mg of oral ibrexafungerp for one, three or seven consecutive days determined by their underlying complicating condition, including immunocompromised state. Complicated patients include patients with recurrent VVC, those with VVC caused by non-albicans *Candida* species and those with diabetes, immunocompromising conditions (e.g., HIV), or immunosuppressive therapy (e.g., corticosteroids). The VANQUISH study will be conducted in approximately 25 centers in the U.S. and we are targeting to have data from this study in the first half of 2024.

Preclinical Developments

In the fourth quarter of 2022, we announced that a $3.0 million National Institutes of Health (NIH) grant was awarded to Case Western Reserve University researchers to study our second generation fungerp (SCY-247). SCY-247 is a broad-spectrum, antifungal under development by us and has as a potential oral and IV systemic therapeutic option for multiple drug-resistant pathogens. The grant is intended the further characterize the potential of SCY-247 to fight *Candida auris*, a multidrug-resistant pathogen named as an "urgent threat" by the Centers for Disease Control (CDC) and included in the "critical priority group" on the World Health Organization (WHO) fungal priority pathogens list (FPPL). Previous preclinical investigations

with SCY-247 have reported potent antifungal activity in in vitro studies, favorable pharmacokinetic profile and promising efficacy in mice models of invasive candidiasis. We plan to continue progressing the development of SCY-247 as a next generation fungerp in the fight against life-threatening fungal diseases.

Key Development Milestones

We are seeking to achieve the following key milestones in the next 12 months:

- close the transactions contemplated by the License Agreement with GSK in the second quarter of 2023;
- continue to advance enrollment of the MARIO study, a global Phase 3 study to evaluate ibrexafungerp as an oral step-down treatment for IC in the hospital setting;
- provide topline data for the FURI and CARES studies in first half of 2024;
- should the GSK Closing not occur, initiate a Phase 2 study of the liposomal IV formulation of ibrexafungerp in 2023; and
- provide topline data for the Phase 2 SCYNERGIA study in the first half of 2023.

Our Strategy

Key elements of our strategy include:

- to close the transactions contemplated by the License Agreement with GSK in the second quarter of 2023;
- to further develop ibrexafungerp and obtain regulatory approval in major commercial markets for our key indications: invasive candidiasis, refractory invasive fungal infections, and invasive aspergillosis;
- should the GSK Closing not occur, to contract with commercial partners to develop and commercialize ibrexafungerp outside of the U.S.;
- to leverage our strong scientific team to pursue the development of other internal proprietary compounds; and
- to assess external opportunities for in-licensing to expand our development pipeline and add products for commercialization.

Ibrexafungerp Target Product Profile

Ibrexafungerp, the first agent in a novel antifungal class, acts through the inhibition of the glucan synthase complex, an established target in antifungal therapeutics. Ibrexafungerp is being developed as oral and IV formulations and has demonstrated potent activity against a large collection of medically relevant strains of *Candida* and *Aspergillus* genera, including multidrug-resistant strains, as well as *Pneumocystis, Coccidioides, Histoplasma* and *Blastomyces* genera. Additionally, ibrexafungerp has shown *in vitro*, *in vivo* and clinical activity against multidrug-resistant organisms such as *Candida auris* and synergistic/additive activity in combination with isavuconazole against *Aspergillus* strains and in

combination with amphotericin B against fungi causing mucormycosis. Ibrexafungerp has unique attributes that define its potential to address significant unmet medical needs and provide considerable commercial opportunities, including:

- oral bioavailability, unlike other glucan synthase inhibitors, allowing for convenient long-term outpatient use;
- broad activity against Candida, Aspergillus, Pneumocystis, Coccidioides, Histoplasma and Blastomyces strains;
- distinct chemical structure from other glucan synthase inhibitors, providing a unique spectrum of activity and pharmacokinetic profile;
- activity against azole-resistant and most echinocandin-resistant Candida strains, including Candida auris and multidrug-resistant strains;
- activity against azole-resistant Aspergillus strains;
- fungicidal (i.e., killing the fungi) capabilities against the Candida genus compared to azoles, which are fungistatic (i.e., only inhibiting the growth of fungi);
- high tissue penetration, allowing high concentrations in the organs commonly affected by fungal infections;
- generally well tolerated with over 1,600 subjects and patients exposed; and
- 20-hour half-life with a low risk of drug-drug interactions.

We believe that ibrexafungerp, if approved, has the potential to address significant gaps with commercially available therapies in the following indications:

- invasive candidiasis (including resistant infections);
- invasive aspergillosis (including resistant infections); and
- refractory invasive fungal infections.

In the future, we (or our licensee GSK following the GSK Closing) may also consider other indications for ibrexafungerp for which longer oral antifungal regimens are typically needed and would benefit from the broad-spectrum activity, favorable safety profile and low potential for drug-drug interactions, including for the treatment of chronic fungal infections and for prophylaxis.

For the treatment of invasive fungal infections, we expect that prescribing physicians will be located at major medical centers, where physicians specializing in critical care, infectious disease specialists, and physicians treating immune compromised or immuno-suppressed patients, such as oncologists and those performing solid organ transplants and stem cell transplants, are likely to be found.

Market Opportunity

Vaginal Yeast Infections

VVC, commonly known as a vaginal yeast infection due to *Candida*, is the second most common cause of vaginitis. Although these infections are frequently caused by *Candida albicans*, infections caused by fluconazole-resistant and non-albicans *Candida* strains, such as *Candida glabrata*, have been reported to be on the rise. An estimated 70-75% of women worldwide will have at least one episode of VVC in their lifetime, and 40-50% of them will experience multiple episodes. VVC can be associated with substantial morbidity, including significant genital discomfort (pain, itching, burning), reduced sexual pleasure and activity, psychological distress (stress, depression, anxiety), embarrassment, reduced physical activity, and loss of productivity. Typical VVC symptoms include pruritus, vaginal soreness, irritation, excoriation of vaginal mucosa and abnormal vaginal discharge.

Current treatments for VVC include several topical azole antifungals and oral fluconazole, which is the only (other than BREXAFEMME) orally administered antifungal currently approved for the treatment of VVC in the U.S. and which accounts for over 90% of the prescriptions for VVC written each year, primarily by obstetrician and gynecologist (OGBYN) offices. Fluconazole reported a 55% therapeutic cure rate in its label, which now also includes warnings of potential fetal harm, illustrating the need for new oral alternatives. In addition, there are many women with persistent (chronic) infections, recurrent infections (four or more recurrences in a 12-month period), non-*albicans* / azole-resistant *Candida* strains (e.g., *Candida glabrata*), diabetic patients, especially with poorly controlled glycemia, and obese patients that could potentially benefit from a non-azole treatment. Except for BREXAFEMME, there are only azole class treatments available for women suffering from VVC with no other approved alternative class in the U.S. When a patient fails fluconazole therapy, patients typically are treated with more fluconazole or a topical azole. Women with VVC could benefit from a non-azole, and preferably oral, treatment option.

We believe BREXAFEMME has the potential to address vaginal yeast infections across a broad range of patients and could be an ideal treatment option for many patients for whom current treatment options are suboptimal. Despite yeast infections being so common and prevalent, with millions of women suffering from it every year, it is still an under-appreciated, under-reported, and under-served women's health condition. Treatments for VVC have historically included several topical azole antifungals and oral fluconazole. Approximately 80% of VVC sufferers will have more than one yeast infection and over a third of women may have six yeast infections or more in a lifetime. There are over 17 million prescriptions written for VVC in the U.S. annually, all of which (prior to BREXAFEMME) belonged to a single drug class, the azoles. There had been no new oral treatment for VVC in over 25 years other than BREXAFEMME, and we believe health care providers are eager for a novel oral alternative to treat their patients.

BREXAFEMME is the first and only approved oral, non-azole treatment for vaginal yeast infections. We believe that BREXAFEMME's unique combination of features, including being from a novel class with a different mechanism of action, single-day oral dosing, broad spectrum, and fungicidal activity in all *Candida* species (*albicans* and non-*albicans*) including fluconazole-resistant strains, differentiates it from competing products.

Invasive Candidiasis / rIFI

Treatment options for invasive candidiasis are limited to three main drug classes: echinocandins, azoles, and amphotericin B. The echinocandins are considered the first line recommended therapy in most invasive candidiasis settings. Because the echinocandins can be administered only intravenously, orally administered azoles are often used as step-down agents after initial IV echinocandin therapy. However, antifungal treatment duration for invasive candidiasis typically extends for several weeks and patients for whom the azoles are not a suitable therapy due to resistance, intolerance, or risk of drug-to-drug interaction are restricted to use IV therapy for several weeks. Amphotericin B is also only available via IV administration and is associated with a significant risk of renal toxicity and infusion reactions, making it an unsuitable option in settings where there is underlying, or high risk of, renal impairment. Due to significant monitoring issues, Amphotericin B is also less desirable for outpatient parenteral administration. The echinocandins are typically well tolerated but clinical resistance is rising in many centers, due to development of mutations in the fks genes leading to echinocandin resistance and shift species with natural resistance as well as the rise of novel drug resistant species, such as *Candida auris*. When resistance develops, the available treatment options may be less efficacious or more toxic. The phenomenon of multi-drug resistance is also reported among isolates of different species of *Candida*, making the management of patients suffering from these infections extraordinarily challenging, considering the very limited treatment options available. Specifically, 90% of *Candida auris* isolates have been reported to be resistant to at least one antifungal agent and 30% isolates resistant to at least two antifungals.

There is a clear need for new antifungal treatment options for patients with invasive candidiasis that are refractory or intolerant to available therapies as well as for those who would benefit from oral therapy. We believe ibrexafungerp has the potential to address many of these unmet needs by providing a well-tolerated oral antifungal agent, with low risk for drug-drug interactions that has activity against azole-resistant and most echinocandin-resistant strains.

Invasive Aspergillosis

Current treatment guidelines for IA in the U.S. and in Europe recommend the use of azoles (itraconazole, voriconazole or isavuconazole) as the initial first-line therapy. However, patients face unsatisfactory clinical outcomes with mortality rates ranging from 30% to 80% (depending on the stage of infection and the host underlying disease) and long treatment durations. Additionally, current azole therapies often exhibit drug-drug interactions, and the recent emergence of *A. fumigatus* azole-resistance is increasingly becoming of clinical concern worldwide.

Due to the significant rate of resistance in some countries, combination antifungal therapy as first-line treatment for patients suspected of IA is recommended. The combination of voriconazole or isavuconazole with a glucan synthesis inhibitor agent (IV echinocandin) is recommended at least until results of resistance testing are obtained. A previous study, by Marr et al. in IA patients demonstrated that the combination of an IV echinocandin and an IV/oral azole for two weeks followed by an oral azole alone for four additional weeks improved outcomes in certain patient subgroups. In this study, the combination regimen was given for only two weeks because of the limitations of using an IV echinocandin long-term in the outpatient setting. We believe that oral ibrexafungerp, if approved in combination with standard of care for the treatment of IA, would allow patients to receive the desired combination treatment of two agents with different mechanisms of action for the full six to twelve weeks of therapy, potentially leading to better outcomes.

Competition for Ibrexafungerp

Our competitors include large pharmaceutical and biotechnology companies, and specialty pharmaceutical and generic drug companies. The leading antifungal drugs representing each main class are as follows:

Azoles. Noxafil® (posaconazole) marketed by Merck and Cresemba® (isavuconazole), approved in the U.S. and other global markets and marketed by Astellas in the U.S.; Diflucan® (fluconazole), Pfizer, off-patent with multiple generics,

Terazol (terconazole), Jannsen, off-patent with multiple generics, Gynazole (butoconazole), Perrigo, off patent with multiple generics;

Echinocandins. Cancidas® (caspofungin), a product that became generic in March 2017, and Mycamine® (micafungin), a generic product. Pfizer markets the echinocandin Eraxis® (anidulafungin); and

Polyenes. AmBisome® (liposomal amphotericin B), a product sold by Gilead in Europe, by Astellas in the U.S. and by Dainippon-Sumitomo in Japan.

Pfizer, Merck, Astellas, and Gilead are all large pharmaceutical companies with significant experience and financial resources in the marketing and sale of specialty pharmaceuticals. Various other producers market and sell generic oral voriconazole, fluconazole and itraconazole.

The VVC market has three generic prescription agents, fluconazole (oral), terconazole and butoconazole (topical), manufactured by multiple generic companies. There is limited to no marketing to support these generic products. In 2022, oral oteseconazole (brand name Vivjoa), developed and marketed by Mycovia Pharmaceuticals, Inc., was approved for the reduction in the incidence of recurrent vulvovaginal candidiasis in women who are not of reproductive potential. Recently, in March 2023, the long-acting IV echinocandin Rezafungin (brand name Rezzayo) being developed by Cidara Therapeutics, Inc.and marketed by Melinta Therapeutics, was approved for the treatment of candidemia and invasive candidiasis in adults with limited or no alternative treatment options. Other antifungals in development include Fosmanogepix (APX-001) being developed by Amplyx Pharmaceuticals Inc., the polyene amphotericin B oral formulation MAT2203 being developed by Matinas BioPharma Holdings Inc., and Olorofim (F901318) being developed by F2G Limited. These companies may have greater resources than ours.

We believe that ibrexafungerp has the ability to perform well in the future fungal infection market given the limited competitive marketplace, the unmet medical need, and the often high mortality rate of many of these infections. The key competitive factors affecting the success of ibrexafungerp, if approved, are likely to be its efficacy, safety, convenience, use in outpatient settings, the level of generic competition and the availability of reimbursement from government and other third-party payors. If approved, we believe that ibrexafungerp's unique features, including being from a novel antifungal class, broad-spectrum of activity including resistant strains, IV and oral formulations, fungicidal activity versus *Candida*, high tissue penetration, and favorable safety profile, will differentiate it from competing products and allow premium pricing to generics and other competing products.

The commercial opportunity for ibrexafungerp could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we or GSK may develop. Competitors also may obtain FDA, or other regulatory, approval for their products more rapidly than we or GSK obtains approval for our ibrexafungerp products. In addition, the commercial success of ibrexafungerp may be affected because in many cases insurers or other third-party payors seek to encourage the use of generic products. In the azole class, fluconazole, itraconazole, posaconazole, and oral voriconazole are generic. Caspofungin, the largest selling echinocandin, is now available on a generic basis. If approved, we believe ibrexafungerp will be capable of delivering value supportive of premium pricing over competitive generic products.

Manufacturing and Supply of Ibrexafungerp

We have agreements with external vendors that are capable of supplying drug substance and of producing drug product to support ongoing and planned clinical trials, as well as for commercial product. However, we do not own or operate and do not intend to own or operate facilities for manufacturing, storage and distribution, or testing of drug substance or drug product. We have relied on third-party contract manufacturers for synthesis of our clinical compounds and manufacture of drug product. We expect to continue to rely on either existing or alternative third-party manufacturers to supply ibrexafungerp for our performance of clinical trials and for supplying GSK needs for clinical and commercial product until it obtains its own source of supply.

Ibrexafungerp is a semi-synthetic compound. Thus, the manufacturing process for ibrexafungerp involves fermentation and synthetic chemical steps. The synthetic process does not require any specialized equipment and uses readily sourced intermediates. At commercial scale, we expect cost of goods for ibrexafungerp to be similar to that of other small molecule drugs. We have negotiated agreements with our primary contract manufacturers to produce both drug product and drug substance for our current clinical trials and for GSK's clinical and commercial needs.

We estimate our supplies on hand as well as those we plan to produce for the oral formulation of ibrexafungerp are sufficient to supply our ongoing clinical trials as well as to support GSK's clinical and commercial needs. Additional batches of both oral and IV ibrexafungerp drug product will be manufactured as needed to support the subsequent stages of clinical development plan and commercial supply requirements.

A drug manufacturing program subject to extensive governmental regulations requires robust quality assurance systems and experienced personnel with the relevant technical and regulatory expertise as well as strong project management skills. We believe we have a team that is capable of managing these activities until GSK assumes responsibility for them pursuant to the License Agreement.

The primary third-party vendors with which we have agreements in place to support manufacturing and supply both for clinical development and commercial needs have the required capabilities with respect to facilities, equipment and technical expertise, quality systems that meet global regulatory and compliance requirements, satisfactory regulatory inspection history from relevant health authorities and proven track records in supplying drug substance and drug product for late-stage clinical and commercial use.

Collaborations and Licensing Agreements Associated with Our Core Drug Development Operations

We have a number of licensing and collaboration agreements associated with our core drug development operations, including the following:

GSK

On March 30, 2023 we entered into a License Agreement with GSK. Pursuant to the terms of the License Agreement, we granted GSK an exclusive (even as to us and our affiliates), royalty-bearing, sublicensable license for the development, manufacture, and commercialization of ibrexafungerp, including the approved product BREXAFEMME, for all indications, in the GSK Territory. If the existing licenses granted to or agreements with third parties are terminated with respect to any country, GSK will have an exclusive first right to negotiate with us to add those additional countries to the GSK Territory. We retain rights to all other assets, with GSK receiving a ROFN to any other enfumafungin-derived compounds or products that we may control.

Under the terms of the License Agreement, we will receive an upfront payment of $90 million. We are also eligible to receive potential:

- regulatory approval milestone payments of up to $70 million;
- commercial milestone payments of up to $115 million based on first commercial sale in invasive candidiasis (U.S./EU);
- and sales milestone payments of up to $242.5 million based on annual net sales, with a total of $77.5 million to be paid upon achievement of multiple thresholds up through $200 million; a total of $65 million to be paid upon achievement of multiple thresholds between $300 million and $500 million; and $50 million to be paid at each threshold of $750 million and $1 billion.

We will be responsible for the execution and costs of the ongoing clinical studies of ibrexafungerp but will have the potential to receive up to $75.5 million in success-based development milestones, which are comprised of up to $65 million for the achievement of three interim milestones associated with our continued performance of the ongoing MARIO Study and $10.5 million for the successful completion of the MARIO Study.

In the case of each of the above milestones, such milestone events are defined in the License Agreement. GSK will also pay royalties based on cumulative annual sales to us in the mid-single digit to mid-teen range. These royalty rates are subject to reduction, including in the event of third-party licenses, entry of a generic product, or the expiration of licensed patents. A joint development committee will be established between GSK and us to coordinate and review ongoing development activities of ibrexafungerp. Unless earlier terminated, the License Agreement will expire on a product-by-product and country-by-country basis at the end of the royalty term for such product in such country.

We have the right to terminate the License Agreement upon an uncured material breach by, or bankruptcy of, GSK. GSK has the right to terminate the License Agreement at any time for convenience in its entirety or on a product-by-product and country-by-country basis, upon an uncured material breach by, or bankruptcy of, us, or for safety reasons.

The consummation of the transactions under the License Agreement is subject to the satisfaction of customary closing conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act"); provided, that either we or GSK may terminate the License Agreement if expiration or termination of the applicable waiting period under the HSR Act has not occurred within nine months of the signing of the License Agreement. The parties expect the transactions contemplated by the License Agreement to close in the second quarter of 2023.

Merck

We initially discovered and developed ibrexafungerp through a research collaboration with Merck Sharp & Dohme Corp. (Merck), a subsidiary of Merck & Co., Inc. In May 2013, Merck transferred to us all development and commercialization rights for ibrexafungerp (also known as MK-3118). This decision was made following a review and prioritization of Merck's

infectious disease portfolio. Under the terms of the agreement, we received all human health rights to ibrexafungerp, including all related technical documents, preclinical data, data from the seven Phase 1 trials conducted by Merck, and drug product and drug substance. The agreement continues until expiration of all royalty obligations. The agreement may be terminated if either party is in material breach and fails to remedy the breach after receiving written notice. In January 2014, Merck assigned the patents to us related to ibrexafungerp that it had exclusively licensed to us. Under the terms of the patent assignment, Merck no longer has responsibility to maintain the patents. Merck was originally eligible to receive milestones upon initiation of a Phase 2 clinical study, NDA submission and marketing approvals in each of the U.S., major European markets and Japan that could total up to $19 million. In addition, Merck will receive tiered royalties based on worldwide sales of ibrexafungerp. The aggregate royalties are mid- to high-single digits of net sales, and we expect to pay royalties on net sales of ibrexafungerp to Merck for no more than ten years from first commercial launch, on a country-by-country basis.

In December 2014, we entered into an amendment to the license agreement with Merck that defers the remittance of a milestone payment due to Merck, such that no amount will be due upon initiation of the first phase 2 clinical trial of a product containing the ibrexafungerp compound (the Deferred Milestone). The amendment also increased, in an amount equal to the Deferred Milestone, the milestone payment that will be due upon initiation of the first Phase 3 clinical trial of a product containing the ibrexafungerp compound. In December 2016 and January 2019, we entered into second and third amendments to the license agreement with Merck which clarified what would constitute the initiation of a Phase 3 clinical trial for the purpose of a milestone payment. In January 2019, a milestone payment became due to Merck as a result of the initiation of the VANISH Phase 3 VVC program and it was paid in March 2019.

On December 2, 2020, we entered into a fourth amendment to the license agreement with Merck. The amendment eliminates two cash milestone payments that we would have paid to Merck upon the first filing of a NDA, triggered by the FDA acceptance for filing of our NDA for ibrexafungerp for the treatment of VVC, and first marketing approval in the U.S. in June 2021 for our NDA for ibrexafungerp for the treatment of VVC. These cash milestone payments would have been creditable against future royalties owed to Merck on net sales of ibrexafungerp. With the amendment, these milestones will not be paid in cash and, accordingly, credits will not accrue. Pursuant to the amendment, we will also forfeit the credits against future royalties that had accrued from a prior milestone payment already paid to Merck. All other key terms of the license agreement are unchanged.

Hansoh

In February 2021, we entered into an Exclusive License and Collaboration Agreement (the Agreement) with Hansoh (Shanghai) Health Technology Co., Ltd., and Jiangsu Hansoh Pharmaceutical Group Company Limited (collectively, Hansoh), pursuant to which we granted to Hansoh an exclusive license to research, develop and commercialize ibrexafungerp in the Greater China region, including mainland China, Hong Kong, Macau, and Taiwan. Under the terms of the Agreement, Hansoh shall be responsible for the development, regulatory approval and commercialization of ibrexafungerp in Greater China. We received a $10.0 million upfront payment and will also be eligible to receive up to $112.0 million in development and commercial milestones, plus low double-digit royalties on net product sales. The obligation to pay royalties with respect to sales in a specified region will continue until the later of the date of expiration of all intellectual property and regulatory exclusivity for the product in the region and ten years from the first commercial sale, unless earlier terminated by Hansoh with advanced notice for convenience or under other specified circumstances.

R-Pharm

In August 2013, we entered into an agreement with R-Pharm, CJSC (R-Pharm), a leading supplier of hospital drugs in Russia, granting them exclusive rights to develop and commercialize ibrexafungerp in the field of human health in Russia, Turkey, and certain Balkan, Central Asian, Middle Eastern and North African countries. We retained the right to commercialize ibrexafungerp in the Americas, Europe, and Asia. In November 2014, we entered into a supplemental arrangement with R-Pharm, whereby R-Pharm was informed of the modified IV formulation development plan and R-Pharm agreed to reimburse us for specifically identified IV formulation development and manufacturing costs incurred by us. We received a non-refundable upfront payment of $1.5 million from R-Pharm in August 2013 which was recognized over a period of 70 months and is fully amortized.

Government Regulation

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

U.S. Drug Approval Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA), and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recall requests, product seizures, total or partial suspension of production or distribution, injunctions, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice (GLP) regulations;
- submission to the FDA of an investigational new drug application (IND) which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice (GCP) to establish the safety and efficacy of the proposed drug for each indication, subject to on-going IRB review;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current Good manufacturing practice (cGMP) regulations and guidance, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

After evaluating the NDA and all related information, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health (NIH) for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which in some cases may overlap or be combined:

Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

Phase 2: The drug is administered to a limited patient population with the target disease to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3: The drug is administered to an expanded patient population with the target disease, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials sometimes cannot be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval. Such post-approval trials are typically referred to as Phase 4 studies.

In some circumstances, the FDA may also order a sponsor to conduct post-approval clinical trials if new safety information arises raising questions about the drug's risk-benefit profile. Those clinical trials are typically referred to as Post-Marketing Requirements (PMRs).

GAIN Act

The FDA has various expedited development programs, including break-through therapy, fast track designation and priority review, that are intended to expedite or simplify the process for the development and FDA review of drugs that meet certain qualifications. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

The GAIN Act is intended to encourage development of new antibacterial and antifungal drugs for the treatment of serious or life-threatening infections by providing certain benefits to sponsors, including extended exclusivity periods, fast track and priority review. To be eligible for these benefits a product in development must seek and be awarded designation as a Qualified Infectious Disease Product (QIDP).

To qualify as a QIDP according to the criteria established in the GAIN Act, a product must be an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including, those:

- caused by an antifungal resistant pathogen, including novel or emerging infectious pathogens; or
- qualifying pathogens listed by the FDA in accordance with the GAIN Act.

Fast Track Designation

The FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor's request.

If a drug candidate is granted Fast Track designation, the sponsor may engage in more frequent interactions with the FDA, and the FDA may review sections of the NDA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Post Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications, manufacturing changes or other labeling claims, are subject to further testing requirements and prior FDA review and approval. There also are continuing annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as application fees for supplemental applications with clinical data.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label, although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications. However, pharmaceutical companies may share truthful and not misleading information that is otherwise consistent with the labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting their promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of regulatory protection to the term of any existing exclusivity, including the non-patent exclusivity periods described above, and to the regulatory term of any patent that has been submitted to FDA for the approved drug product. This six-month exclusivity may be granted based on the voluntary completion of a pediatric study or studies in accordance with an FDA-issued "Written Request" for such a study or studies.

Qualified Infectious Disease Product Exclusivity

If the NDA for a QIDP is approved by the FDA, the FDA will extend by an additional five years any non-patent marketing exclusivity period awarded, such as a five-year exclusivity period awarded for a new chemical entity. This extension is in addition to any pediatric exclusivity extension awarded. Eligibility for the extension will be denied if the product is approved for uses that would not meet the definition of a QIDP.

Data Privacy and Security

In the ordinary course of our business, we may process confidential, proprietary, and sensitive information, including personal data. Accordingly, we are, or may become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy and security. Such obligations may include, without limitation, the Federal Trade Commission Act, the California Consumer Privacy Act of 2018 (CCPA), the Canadian Personal Information Protection and Electronic Documents Act, Canada's Anti-Spam Legislation, the European Union's General Data Protection Regulation 2016/679 (EU GDPR), the EU GDPR as it forms part of United Kingdom (UK) law by virtue of section 3 of the European Union (Withdrawal) Act 2018 (UK GDPR), and the Payment Card Industry Data Security Standard (PCI DSS). Several states within the United States have enacted or proposed data privacy and

security laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act. Additionally, we are, or may become, subject to various U.S. federal and state consumer protection laws which require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

The CCPA and EU GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing that may increase our compliance obligations and exposure for any noncompliance. For example, the CCPA imposes obligations on covered businesses to provide specific disclosures related to a business's collection, use, and disclosure of personal data and to respond to certain requests from California residents related to their personal data (for example, requests to know of the business's personal data processing activities, to delete the individual's personal data, and to opt out of certain personal data disclosures). Also, the CCPA provides for civil penalties and a private right of action for data breaches which may include an award of statutory damages. In addition, the California Privacy Rights Act of 2020 (CPRA), effective January 1, 2023, expanded the CCPA by, among other things, giving California residents the ability to limit use of certain sensitive personal data, establishing restrictions on personal data retention, expanding the types of data breaches that are subject to the CCPA's private right of action, and establishing a new California Privacy Protection Agency to implement and enforce the new law.

Foreign data privacy and security laws (including but not limited to the EU GDPR and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances.

See the section titled "Risk Factors" for additional information about the laws and regulations to which we may become subject and about the risks to our business associated with such laws and regulations.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States our activities are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS, such as the Office of Inspector General, the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, in the United States, sales, marketing and scientific and educational programs also must comply with state and federal fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws. These laws include the following:

- the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal civil and criminal false claims laws, including the civil False Claims Act that can be enforced by private citizens through civil whistleblower or qui tam actions and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value 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 information regarding ownership and investment interests held by physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates," that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as analogous state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third-party payors, including private insurers.

For example, sales, marketing and scientific/educational grant programs must comply with the federal and state anti-fraud and abuse laws, false claims laws, the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and payment transparency laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including civil, criminal and administrative sanctions, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, integrity oversight and reporting obligations, and contractual damages.

Foreign Regulation

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Pharmaceutical Coverage, Pricing and Reimbursement

Our ability to commercialize BREXAFEMME and any of our product candidates successfully will depend in part on the extent to which the United States and foreign governmental authorities, private health insurers and other third-party payors establish appropriate coverage and reimbursement levels for our product candidates and related treatments. In many of the markets where we would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to direct price controls (by law) and to drug reimbursement programs with varying price control mechanisms. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. One third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly.

Increasingly, third party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third party payors may limit coverage to specific products on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. The Company may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of its products. As a result, the coverage determination process is often a time-consuming and costly process that will require the Company to provide scientific and clinical support for the use of its products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Additionally, third-party payors may refuse to include a particular branded drug in their formularies when a competing generic product is available. 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. Further, coverage policies and third-party reimbursement rates may change at any time.

Public and private health care payors control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private health care payors limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or that are supported by other appropriate evidence (for example, published medical literature) and appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA.

Healthcare Reform

In the United States and some foreign jurisdictions there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system to contain costs, improve quality, and expand access to care. For example, in the United States the Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. There have been executive, judicial and congressional challenges to certain aspects of the Affordable Care Act. For example, 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, 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 also unclear how such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and the Company's business.

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 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 2031 unless additional Congressional action is taken.. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for the Company's drugs, if approved, and accordingly, the Company's financial operations.

There also has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices, which has resulted in several 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 drug 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, 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 HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. Additionally, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Intellectual Property

We strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining patents intended to cover our product candidates and compositions, and their methods of use and other inventions that are commercially important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

As of March 1, 2023, we are the owner of more than ten issued U.S. patents and more than 125 issued non-U.S. patents with claims to novel compounds, compositions containing them, processes for their preparation, and their uses as pharmaceutical agents, with terms expiring between 2027 and 2038. Of these patents, six U.S. patents relate to ibrexafungerp. We are actively pursuing several U.S. patent applications and many non-U.S. patent applications in multiple jurisdictions worldwide.

Ibrexafungerp is protected in the United States by an issued composition of matter patent (U.S. Patent No. 8,188,085); three issued patents related to ibrexafungerp salts and polymorphs, including the citrate salt used in BREXAFEMME and our ongoing clinical trials; and two patents covering uses of ibrexafungerp in treatment or prevention of fungal infections. The ‘085 patent is currently set to expire in 2030. We have applied for patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) and believe that the term of the ‘085 patent will be extended into 2035. The three patents covering the citrate salt of ibrexafungerp expire in 2035. The two patents covering uses of ibrexafungerp expire in 2038. The ibrexafungerp composition of matter is covered by a patent in more than 60 jurisdictions worldwide, with several more patent applications pending. Additional patent applications related to ibrexafungerp’s formulations and use as an antifungal agent have been filed and are currently pending. If granted, the new patent families could extend the patent protection for certain ibrexafungerp formulations or uses up to 2040. For this and more comprehensive risks related to our proprietary technology and processes, please see the section on “Risk Factors-Risks Relating to Our Intellectual Property.”

Employees

As of March 1, 2023, we had 36 employees, all of whom were employed on a full-time basis. Our employees are engaged in administration, accounting and finance, research, clinical development, manufacturing, and business development functions. We believe our relations with our employees are good.

Corporate Information

We were incorporated in the State of Delaware on November 4, 1999. Our corporate headquarters are located at 1 Evertrust Plaza, 13th Floor, Jersey City, New Jersey 07302.

Our corporate website address is www.scynexis.com. Our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available free of charge on our website. The information contained on, or that can be accessed through, our website is not part of this Annual Report, and the inclusion of our website address in this Annual Report is an inactive textual reference only.

ITEM 1A. RISK FACTORS

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. Further, the risks below are with respect to our company at the current time, and some of the risks described below may change if/when the transaction contemplated by the License Agreement with GSK closes.

Risks Relating to Our Financial Condition and Need for Additional Capital

We have entered into a License Agreement with GSK, which is subject to closing conditions, including expiration or termination of the HSR waiting period, and if we are not able to close the transaction contemplated by the License Agreement we will not be able to receive the benefits expected from the License Agreement, which would materially and adversely affect our prospects for generating revenue from BREXAFEMME and ibrexafungerp.

In March 2023, we entered into a License Agreement with GSK, and the consummation of the transactions under the License Agreement is subject to the satisfaction of customary closing conditions, including the expiration or termination of the applicable waiting period under the HSR Act. If the closing conditions are not met, then absent a waiver from GSK we will not be able to close the transaction contemplated by the License Agreement. If this were to occur, then we would not be able to realize the benefits we expect from the License Agreement, including the potential to receive the development, regulatory, commercial and sales milestones, and royalties, contemplated by the License Agreement, and we would have expended significant time, money and effort in the development and commercialization of BREXAFEMME, which has been on the market since September 2021, and may not be able to realize a return on that investment.

Even if the License Agreement with GSK closes, we may not be able to realize the benefits we expect under the License Agreement if we are not able to develop ibrexafungerp.

Even if the License Agreement with GSK closes, our ability to generate revenues under the 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 License Agreement, which would materially and adversely affect our business and operating results.

We have never been profitable, we have only one product approved for commercial sale, and to date we have generated limited revenue from product sales. As a result, our ability to curtail our losses and reach profitability is unproven, and we may never achieve or sustain profitability.

We are not profitable and do not expect to be profitable in the foreseeable future. We have incurred net losses in each year since our inception, including a net loss of $62.8 million for the year ended December 31, 2022. As of December 31, 2022, we had an accumulated deficit of approximately $422.3 million. As discussed in Note 1 to the financial statements included in this Annual Report on Form 10-K, we have incurred significant losses and negative cash flows from operations and have limited capital resources to fund ongoing operations which raises substantial doubt about our ability to continue as a going concern. On a prospective basis, our strategic focus, along with the commitment of our financial resources, will be directed towards the development of ibrexafungerp. We had cash, cash equivalents, and short-term investments of $73.5 million as of December 31, 2022. 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 clinical studies for ibrexafungerp, which are difficult for us to predict;
- 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;
- our ability to close the transactions contemplated by the License Agreement with GSK;
- 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.

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 and commercialize 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 loan payable 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.

On May 13, 2021, we entered into a loan payable with Hercules, as administrative agent and collateral agent (in such capacity, the Agent) and a lender, and SVB, as a lender (SVB, and collectively with Hercules in such capacity, the Lenders) for an aggregate principal amount of up to $60.0 million. Until we have repaid such indebtedness, the loan payable and security agreement subjects us to various customary covenants, including requirements as to financial reporting and insurance, and restrictions on our ability to dispose of our business or property, to change our line of business, to liquidate or dissolve, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on our property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock, to redeem capital stock, to enter into licensing agreements, to engage in transactions with affiliates, or to encumber our intellectual property. In connection with the entering into of the License Agreement, we entered into a First Amendment and Consent to Loan and Security Agreement with the Lenders pursuant to which the Lenders consented to us entering into the License Agreement and we agreed to pay to the Lenders an amount equal to the sum of (i) all outstanding principal plus all accrued and unpaid interest with respect to the amounts loaned under the Loan Agreement (approximately $35.4 million), (ii) the prepayment fee payable under Loan Agreement ($262,500), (iii) the final payment payable under Loan Agreement ($1,382,500), and (iv) all other sums, if any, that shall have become due and payable with respect to loan advances under the Loan Agreement. These payments by us will become due upon the earliest of (A) one business day following receipt by us of the $90 million upfront payment payable to us under the License Agreement, (B) June 1, 2023, or (C) the termination of the License Agreement.

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 COVID-19 and the conflict between Ukraine and Russia and related sanctions, bank failures, and increasing inflation rates 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.

For example, on March 10, 2023, we had a banking relationship with SVB, as described above. As of the closure of SVB on March 10, 2023, we held approximately $0.3 million in cash on deposit and approximately $7.0 million in a money market account with SVB who was administering the account as our agent. Our remaining cash, cash equivalents and short-term investments are primarily held in a money market account and in U.S. treasury securities that are unaffiliated with SVB and held with another financial institution acting as custodian, but which SVB administers on our behalf. We were able to access all cash, cash equivalents and short-term investments held at or through SVB and at our financial institution custodians. SVB was closed on March 10, 2023 by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. On March 12, 2023, the U.S. Treasury, Federal Reserve, and FDIC announced that SVB depositors would have access to all of their money starting March 13, 2023. While we have not experienced any losses in such accounts, the recent failure of SVB exposed us to significant credit risk prior to the completion by the FDIC of the resolution of SVB in a manner

that fully protected all depositors. Our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

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 us, or by GSK following the GSK Closing, 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, 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 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 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.

Merck completed seven Phase 1 clinical trials of ibrexafungerp and we have completed 17 Phase 1 clinical trials, four Phase 2 trials, and have initiated six Phase 3 trials, three of which have been completed and three of which are ongoing. 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 in the event that we are able to obtain FDA approval of 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.

If regulatory approval of the IV formulation of ibrexafungerp is not obtained, ibrexafungerp may not achieve broad market acceptance and sales will be limited.

On March 2, 2017, we announced that the FDA had placed a clinical hold on our IV formulation, instructing us to hold the initiation of any new clinical studies with our IV formulation until the FDA completes a review of all available pre-clinical and clinical data of the IV formulation of ibrexafungerp. In January 2018, we announced encouraging pre-clinical results for the prototype liposomal IV formulation of ibrexafungerp, showing improved local tolerability profile at the infusion site in head-to-head pre-clinical evaluations with the cyclodextrin-based IV formulation. In August 2018, we announced that as part of our development plans, the process for the liposomal formulation was transferred for scale-up purposes at a manufacturing site intended to provide clinical supplies. Additional preclinical evaluations were performed with the scaled-up formulation, which unexpectedly revealed differences in tolerability at the injection site, delaying advancement of the IV product into human trials. As it is generally recognized that changes to manufacturing processes and/or scale-up can impact the characteristics of drug products, particularly for more technically complex formulations such as liposomal products, we are currently working with our vendors and CMC experts to enable us to resume the pre-IND pre-clinical activities for the IV formulation of ibrexafungerp in the U.S. If the FDA does not permit us to initiate new clinical studies with our IV formulation, or following the GSK Closing GSK determines not to pursue the IV formulation, we will not be able to develop and commercialize an IV formulation of ibrexafungerp, which would harm our business prospects or our ability to receive payments with respect to the IV formulation under the License Agreement with GSK.

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 in a Phase 1 study. 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.

If we are unable to establish an effective marketing infrastructure, we may not be able to successfully commercialize ibrexafungerp and any future product candidates we may seek to develop.

In the event that we are able to obtain regulatory approval to commercialize our product candidates and determine to develop sales, distribution and marketing capabilities, this would require substantial resources and would be time consuming. The costs incurred in the development of these capabilities, either internally or through a third-party contract sales organization, would be incurred in advance of any approval of a product candidate. In addition, we may not be able to hire a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we intend to target. If we are unable to establish our sales force and marketing capability, our operating results may be adversely affected. 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. We plan to enter into additional sales and marketing or licensing arrangements with third parties for international sales of any approved products. If we are unable to enter into or maintain any such arrangements on acceptable terms, or at all, or these entities fail to perform as we intend under these agreements, we may be unable to market and sell ibrexafungerp or any future product candidates we may seek to develop in these markets.

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 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, 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 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 2031 unless additional Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester.

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 HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Additionally, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries.

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.

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 License Agreement with GSK, who will pay us milestone payments upon the achievement of specified regulatory, commercial and sales milestone events, as well as royalties on sales of ibrexafungerp in those countries in its territory, or determines not to pursue commercialization of ibrexafungerp in those countries, we will not receive any commercial or sales milestone or royalty payments under the 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.

On February 24, 2022, Russia launched an invasion of Ukraine which has resulted in increased volatility in various financial markets and across various sectors. The U.S. and other countries, along with certain international organizations, have imposed economic sanctions on Russia and certain Russian individuals, banking entities and corporations as a response to the invasion. The extent and duration of the military action, resulting sanctions and future market disruptions in the region are impossible 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 the recent emergence and spread of COVID-19, a coronavirus, 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, following the GSK Closing, 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, 2023, we had 36 employees. Further, as we advance ibrexafungerp through preclinical 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. Our coverage is currently limited to $10.0 million per occurrence and $10.0 million in the aggregate per year, as well as additional local country product liability coverage for trials conducted outside of the United States as required by the local country regulations. 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 privacy and data 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, the California Consumer Privacy Act of 2018 (CCPA) 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. Although the CCPA includes exemptions for certain clinical trials data and data collected pursuant to HIPAA, the law may increase our compliance costs and potential liability with respect to other personal data we collect about California residents. Furthermore, the California Privacy Rights Act of 2020 expands the CCPA's requirements, including by adding a new right for individuals to correct their personal data and establishing a new regulatory agency to implement and enforce the law.

Other states, such as Virginia and Colorado, have also passed comprehensive data privacy and security laws, and similar laws are being considered in several other states, as well as at the federal and local levels. 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 and UK's standard contractual clauses, 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 phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), 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, 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, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, 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; 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, including our ability to close the transactions contemplated by the License Agreement with GSK;
- 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, in March 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. Upon conversion of the convertible notes by a holder, the holder will receive shares of our common stock, together, if applicable, with cash in lieu of any fractional share. Holders who convert may also be entitled to receive, under certain circumstances, an interest make-whole payment payable in shares of common stock. In addition, following certain corporate events that occur prior to the maturity date, we will, in certain circumstances, increase the conversion rate for a holder who elects to convert its convertible notes in connection with such a corporate event. To the extent holders of these notes convert the notes, our 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

On March 1, 2018, we entered into a long-term lease agreement for approximately 19,275 square feet of office space in Jersey City, New Jersey. The lease term is until July 2029, and we have the option to renew for two consecutive five-year periods from the end of the first term. We believe that our facilities under this lease are adequate for our purposes for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

We are not party to any legal proceedings for which disclosure is required under this item.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock trades on the Nasdaq Global Market under the symbol “SCYX.”

Stockholders

As of March 1, 2023, there were approximately 50 stockholders of record of our common stock, which excludes stockholders whose shares were held in nominee or street name by brokers. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Further, we are restricted from paying cash dividends under the terms of our Loan Agreement with Hercules and Silicon Valley Bank. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our securities during the fourth quarter of 2022.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Operating results for the year ended December 31, 2022, are not necessarily indicative of results that may occur in future fiscal years. Some of the statements in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" are forward-looking statements. These forward-looking statements are based on management's beliefs and assumptions and on information currently available to our management and involve significant elements of subjective judgment and analysis. Words such as "expects," "will," "anticipates," "targets," "intends," "plans," "believes," "seeks," "estimates," "potential," "should," "could," variations of such words, and similar expressions are intended to identify forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed under the caption "Special Note Regarding Forward Looking Statements" and in "Risk Factors" and elsewhere in this Annual Report on Form 10-K. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this Annual Report.

Overview

SCYNEXIS, Inc. is pioneering innovative medicines to overcome and prevent difficult-to-treat and drug-resistant infections. We are developing our lead product candidate, ibrexafungerp, as a broad-spectrum, intravenous (IV)/oral agent for severe, hospital-based indications. In June 2021 and December 2022, we announced that the U.S. Food and Drug Administration (FDA) approved BREXAFEMME (ibrexafungerp tablets) for treatment of patients with vulvovaginal candidiasis (VVC), also known as vaginal yeast infection, and for the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC), respectively. In October 2022, we announced that were actively pursuing a U.S. commercialization partner to out-license BREXAFEMME in order to refocus our resources on the clinical development of ibrexafungerp for severe, hospital-based indications, while keeping BREXAFEMME on the market and available to patients, and we have ceased actively promoting BREXAFEMME.

Ibrexafungerp, the first representative of a novel class of antifungal agents called triterpenoids, is a structurally distinct glucan synthase inhibitor and has shown in vitro and in vivo activity against a broad range of human fungal pathogens such as *Candida* and *Aspergillus* genera, including multidrug-resistant strains, as well as *Pneumocystis*, *Coccidioides*, *Histoplasma* and *Blastomyces* genera. *Candida* and *Aspergillus* genera are the fungi responsible for approximately 85% of all invasive fungal infections in the United States (U.S.) and Europe. To date, we have characterized the antifungal activity, pharmacokinetics, and safety profile of the oral and IV formulations of ibrexafungerp in multiple in vitro, in vivo, and clinical studies. The FDA has granted Qualified Infectious Disease Product (QIDP) and Fast Track designations to ibrexafungerp for the indications of VVC (including the prevention of recurrent VVC), invasive candidiasis (IC) (including candidemia), and invasive aspergillosis (IA), and has granted Orphan Drug designations for the IC and IA indications. The European Medicines Agency has granted Orphan Medicinal Product designation to ibrexafungerp for IC. These designations may provide us with additional market exclusivity and expedited regulatory paths.

Corporate Strategy Update

In October 2022, we announced a new corporate strategic direction by refocusing our resources on the further clinical development of ibrexafungerp for severe, hospital-based indications with both the oral and liposomal IV formulations, as multiple ongoing Phase 3 studies are progressing for a potential first approval in hospital indications in 2024 and a Phase 2 study of the IV formulation of ibrexafungerp is planned for 2023. Additionally, we concluded the partnership with our contracted commercial sales partner, Amplity Health (Amplity), on November 30, 2022, and we completed a workforce reduction primarily in the commercial function.

On March 30, 2023, we entered into a license agreement (the License Agreement) with GlaxoSmithKline Intellectual Property (No. 3) Limited (GSK). Pursuant to the terms of the License Agreement, we granted GSK an exclusive (even as to us and our affiliates), royalty-bearing, sublicensable license for the development, manufacture, and commercialization of ibrexafungerp, including the approved product BREXAFEMME, for all indications, in all countries other than Greater China and certain other countries already licensed to third parties (the GSK Territory). If the existing licenses granted to or agreements with third parties are terminated with respect to any country, GSK will have an exclusive first right to negotiate with us to add those additional countries to the GSK Territory. We retain rights to all other assets, with GSK receiving a right of first negotiation (ROFN) to any other enfumafungin-derived compounds or products that we may control. The consummation of the transactions under the License Agreement is subject to the satisfaction of customary closing conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the HSR Act); provided, that either we or GSK may terminate the License Agreement if expiration or termination of the applicable waiting period under the HSR Act has not occurred within nine months of the signing of the License Agreement. The parties expect the transactions contemplated by the License Agreement to close in the second quarter of 2023.

Under the terms of the License Agreement, we will receive an upfront payment of $90 million. We are also eligible to receive potential:

- regulatory approval milestone payments of up to $70 million;
- commercial milestone payments of up to $115 million based on first commercial sale in invasive candidiasis (U.S./EU);
- and sales milestone payments of up to $242.5 million based on annual net sales, with a total of $77.5 million to be paid upon achievement of multiple thresholds up through $200 million; a total of $65 million to be paid upon achievement of multiple thresholds between $300 million and $500 million; and $50 million to be paid at each threshold of $750 million and $1 billion.

We will be responsible for the execution and costs of the ongoing clinical studies of ibrexafungerp but will have the potential to receive up to $75.5 million in success-based development milestones, which are comprised of up to $65 million for the achievement of three interim milestones associated with our continued performance of the ongoing MARIO Study and $10.5 million for the successful completion of the MARIO Study. See further details of the License Agreement, including financial terms, as described in Note 16 of Item 8 on this Annual Report.

We, Hercules Capital, Inc. (Hercules Capital) and Silicon Valley Bridge Bank, N.A. (SVB) are party to a Loan and Security Agreement dated as of May 13, 2021 (the Loan Agreement), pursuant to which Hercules Capital, SVB and each of the other lenders from time-to-time party to the Loan and Security Agreement (collectively, the Lenders) loaned to us $35 million. In connection with the entering into of the License Agreement, we entered into a First Amendment and Consent to Loan and Security Agreement with the Lenders pursuant to which the Lenders consented to us entering into the License Agreement and we agreed to pay to the Lenders an amount equal to the sum of (i) all outstanding principal plus all accrued and unpaid interest with respect to the amounts loaned under the Loan Agreement (approximately $35.4 million), (ii) the prepayment fee payable under Loan Agreement ($262,500), (iii) the final payment payable under Loan Agreement ($1,382,500), and (iv) all other sums, if any, that shall have become due and payable with respect to loan advances under the Loan Agreement. These payments by us will become due upon the earliest of (A) one business day following receipt by us of the $90 million upfront payment payable to us under the License Agreement, (B) June 1, 2023, or (C) the termination of the License Agreement.

Dr. Marco Taglietti, our former President and Chief Executive Officer, retired on December 31, 2022 and stepped down from the Board of Directors. David Angulo, M.D., who had served as Chief Medical Officer for the past seven years, became President and Chief Executive Officer and joined the Board of Directors, effective January 1, 2023. Additionally, Ivor Macleod joined as Chief Financial Officer on October 24, 2022. Mr. Macleod has more than thirty years of experience in the life sciences industry, including most recently as Chief Financial Officer of Athersys, Inc. The role of Chief Commercial Officer was eliminated in November 2022, and Christine Coyne, who had served in this leadership role since May 2021, transitioned from us to pursue other opportunities.

BREXAFEMME Update

In June 2021, the FDA approved BREXAFEMME for use in women with VVC. This approval was based on positive results from two Phase 3, randomized, double-blind, placebo-controlled, multi-center studies (VANISH-303 and VANISH-306), in which oral ibrexafungerp demonstrated statistically superior efficacy compared to placebo and a favorable tolerability profile in women with VVC. The FDA granted BREXAFEMME five years of exclusivity extension under the Generating Antibiotic Incentives Now (GAIN) Act, which will be added to any other applicable exclusivity periods, such as the five years of new chemical entity (NCE) exclusivity, for a combined ten-year period of regulatory exclusivity. BREXAFEMME also is protected by multiple patents, including a composition-of-matter patent covering the ibrexafungerp molecule. With patent term extension, this patent is expected to expire in 2035, providing an expected 13 years of protection from generic competitors in the U.S. In December 2022, we announced that the FDA approved a second indication for BREXAFEMME for the reduction in the incidence of RVVC, with the potential for peak U.S. sales combined for the treatment of VVC and RVVC estimated over $400 million.

On March 30, 2023, we entered into the License Agreement with GSK. Pursuant to the terms of the License Agreement, we granted GSK an exclusive (even as to us and our affiliates), royalty-bearing, sublicensable license for the development, manufacture, and commercialization of ibrexafungerp, including the approved product BREXAFEMME, for all indications, in the GSK Territory.

Ibrexafungerp Update

Enrollment is continuing in our prospective, randomized, double-blind, global Phase 3 study to evaluate the efficacy, safety and tolerability of oral ibrexafungerp as a step-down therapy for patients with IC including candidemia following IV echinocandin therapy in the hospital compared to currently available therapies (the MARIO study). Eligible patients with IC will receive treatment with IV echinocandin and will then be switched to either oral ibrexafungerp or a standard of care option, either oral fluconazole or best available therapy for subjects with infections caused by fluconazole non-susceptible strains, once

step-down criteria are met. Approximately 220 patients will be enrolled and randomized in the study, and we expect topline results in the first half of 2024 and a potential approval by the end of 2024.

The primary objective of the study is to determine whether treatment of IC with IV echinocandins followed by oral ibrexafungerp is as effective as treatment with IV echinocandins followed by oral fluconazole (or BAT), the current standard of care. The primary end point of the study will be all-cause mortality at 30 days after initiation of antifungal therapy. Approximately 35,000 cases of IC in the U.S. per year are caused by the *Candida* isolates that are resistant to azoles, a population for which ibrexafungerp could provide a much-needed oral alternative.

We achieved a target enrollment of 200 patients in our Phase 3 FURI study investigating the potential of ibrexafungerp as a treatment for fungal infections that are refractory or intolerant to other antifungals, including infections caused by *Candida auris* (*C. auris*), and anticipate study completion activities in the first half of 2023 with a Data Review Committee review and topline data in the first half of 2024. We also achieved a target enrollment of 30 patients in our Phase 3 CARES study, focused on patients with infections caused by *C. auris* which will follow similar completion and reporting timing to the Phase 3 FURI study. The data from the MARIO study along with data from FURI and CARES studies are intended to be supportive of an NDA submission in 2024 with an anticipated first approval for an indication in the hospital setting later in 2024. If the License Agreement closes, such NDA submission would be made by GSK and any resulting approval would be held by GSK.

We completed our Phase 1 randomized, double-blind, placebo-controlled single and multiple ascending dose study evaluating the safety, tolerability, and pharmacokinetics of the liposomal IV formulation of ibrexafungerp in 64 healthy subjects with treatment durations of up to seven days. The liposomal IV formulation of ibrexafungerp was designed to optimize tolerability and address dose-limiting infusion site irritation adverse events observed with previous formulations. The liposomal IV formulation of ibrexafungerp was generally well tolerated with no serious adverse events reported. The most common adverse events were mostly mild (few moderate) reactions at the infusion site. The dosing was successfully progressed until the target exposure was achieved (i.e., exposure associated with efficacy from animal models). If the License Agreement does not occur, we are planning to begin a Phase 2 study of the liposomal IV formulation in 2023.

We have completed the enrollment of SCYNERGIA, although the number of patients is smaller than initially projected. The prioritization of hospital resources toward addressing COVID-19 has impacted the ability of many institutions to focus on screening and enrolling patients into some clinical trials, including SCYNERGIA. We expect to provide topline data for SCYNERGIA in the first half of 2023.

In the second quarter of 2022, enrollment began in a new Phase 3b, open-label, multicenter study (VANQUISH) to evaluate the efficacy, safety and tolerability of oral ibrexafungerp as a treatment for complicated VVC in patients who have failed treatment with fluconazole, based on mycological and clinical outcomes. The VANQUISH study will enroll approximately 150 complicated VVC patients who will receive 600 mg of oral ibrexafungerp for one, three or seven consecutive days determined by their underlying complicating condition, including immunocompromised state. Complicated patients include patients with recurrent VVC, those with VVC caused by non-albicans Candida species and those with diabetes, immunocompromising conditions (e.g., HIV), or immunosuppressive therapy (e.g., corticosteroids). The VANQUISH study will be conducted in approximately 25 centers in the U.S. and we are targeting to have data from this study in the first half of 2024.

In the fourth quarter of 2022, we announced that a $3.0 million National Institutes of Health (NIH) grant was awarded to Case Western Reserve University researchers to study our second generation fungerp (SCY-247). SCY-247 is a broad-spectrum, antifungal under development by us and has as a potential oral and IV systemic therapeutic option for multiple drug-resistant pathogens. The grant is intended to further characterize the potential of SCY-247 to fight *Candida auris*, a multidrug-resistant pathogen named as an “urgent threat” by the Centers for Disease Control (CDC) and included in the “critical priority group” on the World Health Organization (WHO) fungal priority pathogens list (FPPL). Previous preclinical investigations with SCY-247 have reported potent antifungal activity in *in vitro* studies, favorable pharmacokinetic profile and promising efficacy in mice models of IC. We plan to continue progressing the development of SCY-247 as a next generation fungerp in the fight against life-threatening fungal diseases.

Liquidity

We have operated as a public entity since we completed our initial public offering in May 2014, which we refer to as our IPO. We also completed a follow-on public offering of our common stock in April 2015 and public offerings of our common stock and warrants in June 2016, March 2018, December 2019, December 2020, and April 2022. Our principal source of liquidity is cash, cash equivalents, and short-term investments which totaled $73.5 million as of December 31, 2022 and we have the availability to issue up to $46.2 million of our common stock under our at-the-market facility with Cantor Fitzgerald & Co. (Cantor) and Ladenburg Thalmann & Co. Inc. (Ladenburg). We received $30.0 million in 2021 and received $5.0 million in 2022 under our Loan Agreement with Hercules and Silicon Valley Bank. In March 2023, in connection with the entering into of the License Agreement with GSK, we, Hercules and SVB entered into a First Amendment and Consent to Loan and Security Agreement pursuant to which the lenders under the Loan Agreement consented to us entering into the License

Agreement and we agreed to pay to the lenders an amount equal to the sum of (i) all outstanding principal plus all accrued and unpaid interest with respect to the amounts loaned under the Loan Agreement (approximately $35.4 million), (ii) the prepayment fee payable under Loan Agreement ($262,500), (iii) the final payment payable under Loan Agreement ($1,382,500), and (iv) all other sums, if any, that shall have become due and payable with respect to loan advances under the Loan Agreement. These payments by us will become due upon the earliest of (A) one business day following receipt by us of the $90 million upfront payment payable to us under the License Agreement, (B) June 1, 2023, or (C) the termination of the License Agreement. See "Liquidity and Capital Resources" below for amounts sold under the ATM with Cantor and Ladenburg, and the amounts sold under our common stock purchase agreement with Aspire Capital which expired in October 2022.

We have incurred net losses since our inception, including the year ended December 31, 2022. As of December 31, 2022, our accumulated deficit was $422.3 million. We expect we will continue to incur significant research and development expense as we continue to execute our research and drug development strategy. Consistent with our operating plan, we also expect that we will continue to incur significant selling, general and administrative expenses to support our public reporting company operations and ongoing operations, but that our selling, general and administrative expenses will decrease as we have ceased the active promotional activities associated with BREXAFEMME for the VVC indication. As a result, we will need additional capital to fund our operations, which we may obtain through one or more of equity offerings, debt financings, other non-dilutive third-party funding (e.g., grants), strategic alliances and licensing or collaboration arrangements. We may offer shares of our common stock pursuant to our effective shelf registration statements, including under our ATM.

Components of Operating Results

Revenue

Revenue primarily consists of product sales of BREXAFEMME and a non-refundable upfront payment received under our license agreement with Hansoh.

Cost of Product Revenue

Cost of product revenue consists primarily of distribution, freight expenses, royalties due to Merck, and other manufacturing costs associated with BREXAFEMME. Prior to the regulatory approval of BREXAFEMME on June 1, 2021, we expensed as research and development the costs associated with the third-party manufacture of BREXAFEMME.

Research and Development Expense

Research and development expense consists of expenses incurred while performing research and development activities to discover, develop, or improve potential product candidates we seek to develop. This includes conducting preclinical studies and clinical trials, manufacturing and other development efforts, and activities related to regulatory filings for product candidates. We recognize research and development expenses as they are incurred. Our research and development expense primarily consists of:

- costs related to executing preclinical studies and clinical trials, including development milestones, drug formulation, manufacturing and other development;
- salaries and personnel-related costs, including benefits and any stock-based compensation for personnel performing research and development functions;
- fees paid to clinical research organizations (CROs), vendors, consultants and other third parties who support our product candidate development and intellectual property protection;
- other costs in seeking regulatory approval of our products; and
- allocated overhead.

Ibrexafungerp was the only key research and development project during the periods presented. We expect to continue to incur significant research and development expense for the foreseeable future as we continue our effort to develop ibrexafungerp, and to potentially develop our other product candidates, subject to the availability of additional funding.

The successful development of product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of any product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates.

Selling, General and Administrative Expense

Selling, general and administrative expense consists primarily of salaries and personnel-related costs, including employee benefits and any stock-based compensation. This includes personnel in executive, accounting and finance, commercial, human resources, business development, medical affairs, and administrative support functions. Other expenses include facility-related

costs not otherwise allocated to research and development expense, professional fees for accounting, auditing, tax and legal services, consulting costs for general and administrative purposes, information systems maintenance and marketing efforts.

Other Expense (Income)

Substantially all of our other expense (income) during the periods reported consists of costs associated with:

- fair value adjustments to our warrant and derivative liabilities;
- interest expense;
- amortization of debt issuance costs and discount;
- other income associated with research and development tax credits;
- interest income associated with our held-to-maturity short-term investments and money market account; and
- the expense recognized for the extinguishment of debt.

Income Tax Benefit

To date, we have not been required to pay U.S. federal income taxes because of our current and accumulated net operating losses. For the year ended December 31, 2022, our income tax benefit recognized consists primarily of an income tax benefit associated with the sale of our NOLs and research and development credits.

Results of Operations for the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021, and period-to-period percentage change (dollars in thousands):

	Years Ended December 31,			
	2022	2021	Period-to-Period Change	
Revenue:				
Product revenue, net	$ 4,988	$ 1,113	3,875	348.2%
License agreement revenue	103	12,050	(11,947)	(99.1)%
Total revenue	5,091	13,163	(8,072)	(61.3)%
Operating expenses:				
Cost of product revenue	628	312	316	101.3%
Research and development	27,259	23,773	3,486	14.7%
Selling, general and administrative	62,961	49,916	13,045	26.1%
Total operating expenses	90,848	74,001	16,847	22.8%
Loss from operations	(85,757)	(60,838)	(24,919)	41.0%
Other (income) expense:				
Loss on extinguishment of debt	—	2,725	(2,725)	(100.0)%
Amortization of debt issuance costs and discount	1,589	1,303	286	21.9%
Interest income	(1,415)	(24)	(1,391)	5795.8%
Interest expense	5,198	2,660	2,538	95.4%
Other income	(3)	(13)	10	(76.9)%
Warrant liabilities fair value adjustment	(22,301)	(30,365)	8,064	(26.6)%
Derivative liabilities fair value adjustment	(1,316)	(1,170)	(146)	12.5%
Total other income	(18,248)	(24,884)	6,636	(26.7)%
Loss before taxes	(67,509)	(35,954)	(31,555)	87.8%
Income tax benefit	4,700	3,088	1,612	52.2%
Net Loss	**$ (62,809)**	**$ (32,866)**	**$ (29,943)**	**91.1%**

Revenue. For the year ended December 31, 2022, revenue consists primarily of product sales of BREXAFEMME, for which we began commercialization in the second half of 2021. For the year ended December 31, 2021, revenues consists primarily of a non-refundable upfront payment received under our license agreement with Hansoh.

Cost of Product Revenues. For the year ended December 31, 2022, cost of product revenue consists primarily of distribution, freight, and royalty costs associated with BREXAFEMME. Prior to the regulatory approval of BREXAFEMME on June 1, 2021, we expensed $3.4 million as research and development expense the costs associated with the third-party manufacture of BREXAFEMME which was recognized primarily in 2020. We expect that these quantities of BREXAFEMME previously expensed prior to June 1, 2021, will be sold by us or GSK over approximately the next 12 months.

Research and Development. For the year ended December 31, 2022, research and development expenses increased to $27.3 million from $23.8 million for the year ended December 31, 2021. The increase of $3.5 million, or 14.7%, was primarily driven by an increase of $3.0 million in clinical development expense, an increase of $1.0 million in preclinical expense, an increase of $0.5 million in both salary and stock compensation expense, offset by a decrease of $1.3 million in chemistry, manufacturing, and controls (CMC) expense, and a $0.2 million decrease in other research and development expense.

The $3.0 million increase in clinical development expense for the year ended December 31, 2022, was primarily driven by an increase of $5.3 million in expense associated with the costs for the MARIO study which was initiated in the fourth quarter of 2021, an increase of $1.3 million in expense associated with the VANQUISH study, offset in part by a $3.4 million decrease in expense associated with the CANDLE Phase 3 study which was substantially complete in the first quarter of 2022. The $1.0 million increase in preclinical expense was primarily associated with the expense recognized for certain preclinical studies associated with the IV liposomal formulation conducted in the current period. The $0.5 million increase in both salary and stock compensation expense is primarily driven by the increase in employees in comparison to the prior period and by the increase in restricted stock unit grants made in the first quarter of 2022, respectively. The $1.3 million decrease in CMC expense for the year ended December 31, 2022, was primarily driven by a $0.9 million decrease in expense for third-party drug product manufacturing in the current period.

Selling, General and Administrative. For the year ended December 31, 2022, selling, general and administrative expenses increased to $63.0 million from $49.9 million for the year ended December 31, 2021. The increase of $13.0 million, or 26.1%, was primarily driven by a $8.6 million increase in commercial related expense, an increase of $1.6 million in salary and payroll related costs, and an increase of $1.5 million in professional fees, all primarily due to the costs recognized to support the commercialization of BREXAFEMME, an increase of $1.0 million in stock compensation expense, and an increase of $1.9 million primarily in severance expense associated with our reduction in workforce, offset in part by a decrease of $0.9 million in medical affairs expense and a $0.7 million decrease in business development expense due to the Hansoh license agreement entered into in 2021.

Loss on Extinguishment of Debt. For the year ended December 31, 2021, we recognized a $2.7 million loss on extinguishment of debt associated with the January 2021 conversation of our remaining April 2020 convertible notes.

Amortization of Debt Issuance Costs and Discount. For the years ended December 31, 2022 and 2021, we recognized $1.6 million and $1.3 million in amortization of debt issuance costs and discount. The 2022 and 2021 debt issuance costs and discount for our March 2019 convertible notes primarily consisted of an allocated portion of advisory fees, issuance costs, and the initial fair value of the derivative liability. The 2022 and 2021 debt issuance costs and discount for our Loan Agreement with Hercules Capital, Inc. and Silicon Valley Bank (the Loan Agreement) comprised issuance and commitment costs, customary closing and final fees, and the fair value of the warrants issued in conjunction with the Loan Agreement.

Interest Income. For the years ended December 31, 2022 and 2021, we recognized $1.4 million and $24,000, respectively, in interest income associated with our money market account and short-term investments. The increase in interest income was primarily due to the increase in the interest rate on our money market account.

Interest Expense. For the years ended December 31, 2022 and 2021, we recognized $5.2 million and $2.7 million, respectively, in interest expense associated with our Loan Agreement and convertible debt. The increase in interest expense was primarily driven by the increase in the interest rate associated with the Loan Agreement entered into in May 2021.

Other Income. For the years ended December 31, 2022 and 2021, we recognized $3,000 and $13,000 in other income associated with certain research and development tax credits.

Warrant Liabilities Fair Value Adjustment. For the years ended December 31, 2022 and 2021, we recognized gains of $22.3 million and $30.4 million, respectively, for the fair value adjustment for warrant liabilities primarily due to the decrease in our stock price during the periods.

Derivative Liabilities Fair Value Adjustment. For the years ended December 31, 2022 and 2021, we recognized gains of $1.3 million and $1.2 million, respectively, in the fair value adjustment related to the derivative liabilities primarily due to the decrease in our stock price during the periods.

Income Tax Benefit. For the year ended December 31, 2022, we recognized a $4.7 million income tax benefit associated with the sale of a portion of our NOLs and research and develop1ent credits. For the year ended December 31, 2021, we recognized a $4.1 million income tax benefit associated with the sale of a portion of our NOLs and research and development credits and $1.1 million of tax withholding expense primarily associated with the upfront payment received from Hansoh.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2022, we had cash, cash equivalents, and short-term investments of approximately $73.5 million, compared to cash and cash equivalents of $104.5 million as of December 31, 2021. The decrease in our cash, cash equivalents, and short-term investments was primarily due to the selling, general and administrative expenses in part to support the commercial launch of BREXAFEMME and the continued development costs associated with ibrexafungerp, offset in part due to the $41.8 million in net proceeds we raised from our public offering of our common stock and warrants in April 2022.

We have incurred net losses since our inception, including the year ended December 31, 2022. As of December 31, 2022, our accumulated deficit was $422.3 million. We anticipate that we will continue to incur losses for at least the next several years. As a result, we will need additional capital to fund our operations, which we may obtain through one or more of equity offerings, debt financings, or other non-dilutive third-party funding (e.g., grants), strategic alliances and licensing or collaboration arrangements. We may offer shares of our common stock pursuant to our Form S-3 shelf registration statements. During the year ended December 31, 2022, we sold 137,610 shares of our common stock and received net proceeds of $0.7 million under our at-the-market (ATM) facility, sold 425,000 shares of our common stock and received net proceeds of $1.6 million under our common stock purchase agreement with Aspire Capital, and in February 2022, we received a cash receipt of $4.7 million from a third party for the sale of a portion of our unused New Jersey Net Operating Losses (NOLs) and research and development credits.

Cash Flows

The following table sets forth the significant sources and uses of cash for the years ended December 31, 2022 and 2021 (dollars in thousands):

	Years Ended December 31,	
	2022	2021
Cash, cash equivalents, and restricted cash, January 1	$ 104,702	$ 93,314
Net cash used in operating activities	(79,883)	(54,560)
Net cash used in investing activities	(27,389)	(1,172)
Net cash provided by financing activities	48,602	67,120
Net (decrease) increase in cash, cash equivalents, and restricted cash	(58,670)	11,388
Cash, cash equivalents, and restricted cash, December 31	**$ 46,032**	**$ 104,702**

Operating Activities

The $25.3 million increase in net cash used in operating activities for the year ended December 31, 2022, as compared to the year ended December 31, 2021, was primarily due to the increase in selling, general and administrative expenses to support the commercial launch of BREXAFEMME and the continued development costs associated with ibrexafungerp. In the prior comparable period, we received a cash receipt of $10.0 million from Hansoh, as consideration for the licenses under our agreement with Hansoh in February 2021, that offset selling, general and administrative expenses to support the commercial launch of BREXAFEMME and the continued development costs associated with ibrexafungerp and ongoing operations. Consistent with our operating plan, we also expect that we will continue to incur significant selling, general and administrative expenses to support our public reporting company operations and ongoing operations, but that our selling, general and administrative expenses will decrease as we wind down the promotional activities associated with BREXAFEMME for the VVC indication.

Net cash used in operating activities of $79.9 million for the year ended December 31, 2022, primarily consisted of the $62.8 million net loss adjusted for non-cash charges that included the gain on change in fair value of the warrant liabilities of $22.3 million and stock-based compensation expense of $3.7 million, the gain on change in fair value of the derivative liabilities of $1.3 million, and the amortization of debt issuance costs and discount of $1.6 million, plus a net favorable change in operating assets and liabilities of $0.8 million. The net favorable change in operating assets and liabilities consisted primarily of an increase in accrued expenses, other liabilities and other of $2.3 million due to the increase of $2.4 million in other liabilities associated with the long term deferred fees due to Amplity, a decrease in prepaid expenses, other assets deferred costs and other of $1.6 million primarily due to a $1.1 million decrease in prepaid inventory, offset in part due to a decrease in accounts payable of $1.5 million and an increase in accounts receivable of $1.2 million.

Net cash used in operating activities of $54.6 million for the year ended December 31, 2021, primarily consisted of the $32.9 million net loss adjusted for non-cash charges that included the gain on change in fair value of the warrant liabilities of $30.4 million and stock-based compensation expense of $2.1 million, the gain on change in fair value of the derivative liabilities of $1.2 million, the loss on extinguishment of debt of $2.7 million, and the amortization of debt issuance costs and discount of $1.3 million, plus a net favorable change in operating assets and liabilities of $3.1 million. The net favorable

change in operating assets and liabilities consisted of an increase in accounts payable and accrued expenses of $7.7 million, offset in part by an increase in prepaid expenses, other assets, and deferred costs, accounts receivable, and inventory of $4.6 million. The $7.7 million increase in accounts payable and accrued expenses was primarily due to the increase in accounts payable of $2.6 million as of December 31, 2021 and an increase of $3.4 million for other liabilities associated with the long term deferred fees due to Amplity. The $4.6 million increase in prepaid expenses, other assets, and deferred costs, accounts receivable, and inventory is primarily due to an increase in inventory of $5.3 million, and an increase in accounts receivable of $0.9 million, offset in part by a decrease of $2.9 million in other assets for a receivable that was fully collected in February 2021.

Investing Activities

Net cash used in investing activities of $27.4 million for the year ended December 31, 2022, consisted of purchases of short-term investments.

Net cash used in investing activities of $1.2 million for the year ended December 31, 2021, consisted solely of purchases of intangible assets associated with implementation costs for internal use software.

Financing Activities

Net cash provided by financing activities of $48.6 million for the year ended December 31, 2022, consisted primarily of the gross proceeds of $45.0 million from the April 2022 public offering, the $2.2 million in gross proceeds from common stock issued under our ATM and common stock purchase agreement, and the $5.0 million received from the Loan Agreement, offset in part by payments of offering costs and underwriting discounts and commissions of $3.6 million.

Net cash provided by financing activities of $67.1 million for the year ended December 31, 2021, consisted primarily of (a) gross proceeds from common stock of $32.8 million from the exercise of outstanding warrants in addition to $5.7 million in gross proceeds from common stock sold under our ATM and Aspire facilities, partially offset by related underwriting discounts and commissions and offering expenses totaling $0.2 million, and (b) during the period we received $30.0 million under our Loan Agreement, offset by $1.3 million in payments of loan payable issuance costs associated with the Loan Agreement.

Future Cash Needs and Funding Requirements

To date, we have generated minimal revenue from product sales. We do not know if or when we will be able to generate significant revenue from product sales. In addition, we expect to incur expenses in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. We anticipate that we will need substantial additional funding in connection with our continuing future operations. As discussed in Note 1 to the financial statements included in this Annual Report on Form 10-K, we have incurred significant losses and negative cash flows from operations and have limited capital resources to fund ongoing operations which raises substantial doubt about our ability to continue as a going concern.

We received $30.0 million in 2021 and received $5.0 million in 2022 under our Loan Agreement with Hercules and Silicon Valley Bank. In March 2023, in connection with the entering into of the License Agreement with GSK, we, Hercules and SVB entered into a First Amendment and Consent to Loan and Security Agreement pursuant to which the lenders under the Loan Agreement consented to us entering into the License Agreement and we agreed to pay to the lenders an amount equal to the sum of (i) all outstanding principal plus all accrued and unpaid interest with respect to the amounts loaned under the Loan Agreement (approximately $35.4 million), (ii) the prepayment fee payable under Loan Agreement ($262,500), (iii) the final payment payable under Loan Agreement ($1,382,500), and (iv) all other sums, if any, that shall have become due and payable with respect to loan advances under the Loan Agreement. These payments by us will become due upon the earliest of (A) one business day following receipt by us of the $90 million upfront payment payable to us under the License Agreement, (B) June 1, 2023, or (C) the termination of the License Agreement.

We are continually evaluating our operating plan and assessing the optimal cash utilization for our ibrexafungerp development strategy. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses necessary to complete the development of product candidates.

Our future capital requirements will depend on many factors, including:

- our ability to close the transactions contemplated by the License Agreement with GSK;
- the progress, costs, and the clinical research and development of ibrexafungerp;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the ability of our product candidates to progress through clinical development successfully;

- our need to expand our research and development activities;
- the costs associated with securing, establishing and maintaining commercialization and manufacturing capabilities;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- our need to implement additional, as well as to enhance existing, internal systems and infrastructure, including financial and reporting processes and systems; and
- the economic and other terms, timing and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of net proceeds from equity offerings, debt financings, or other non-dilutive third-party funding (e.g., grants), strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, similar to our Loan Agreement or the convertible senior notes we sold in March 2019 and April 2020, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through sales of assets, other third-party funding, strategic alliances and licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

Critical Accounting Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of our consolidated financial statements requires us to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our consolidated financial statements, as well as the reported revenues and expenses during the reported periods. We evaluate these estimates and judgments on an ongoing basis. We base our assumptions and estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements for the year ended December 31, 2022, included in this Annual Report, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our consolidated financial statements and understanding and evaluating our reported financial results.

Revenue Recognition

Product Revenue, Net

We account for revenue in accordance with Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers* (Topic 606). Under ASC Topic 606, an entity recognizes revenue when its customer obtains control of goods and services, in an amount that reflects the consideration that the entity expects to be entitled in exchange for those goods and services. We perform the following five steps to recognize revenue under ASC Topic 606: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only recognize revenue when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services that will be transferred to the customer. The transaction price for product sales is reduced by variable consideration related to certain gross to net (GTN) adjustments, including chargebacks, rebates, discounts, incentives, and returns, and we will estimate the amount of this variable consideration that should be included in the transaction price using the expected value method.

Information from external sources is used to estimate GTN adjustments. Our estimate of inventory at the wholesalers is based on the projected prescription demand-based sales for our products, as well as our analysis of third-party information, including written and oral information obtained from certain wholesalers with respect to their inventory levels and sell-through to customers and third-party market research data, and our internal information. The inventory information received from

wholesalers is a product of their recordkeeping process and excludes inventory held by intermediaries to whom they sell, such as retailers.

We also use information from external sources to identify prescription trends, patient demand and average selling prices. Our estimates are subject to inherent limitations of estimates that rely on third-party information, as certain third-party information was itself in the form of estimates, and reflect other limitations including lags between the date as of which third-party information is generated and the date on which we receive third-party information. Our significant GTN adjustments are further described below:

- Voluntary Patient Assistance Programs – Through vendors, we offer copay assistance to provide financial assistance to patients for the portion of their prescription cost that is not covered by payors. The reduction in product revenue due to the copay programs is based on an estimate of claims and costs per claim that we expect to receive associated with product revenue that have been recognized. This includes potential product revenue that remains in the distribution channel at the end of a reporting period.
- Wholesaler Fees and Trade Discounts – We offer discounts and pays certain distributor service fees primarily at contracted rates. These are recorded as a reduction in product revenue based on distributors' purchases and the applicable discount rate.
- Chargebacks - For certain entities, pricing on BREXAFEMME is extended below wholesaler list price. Entities that purchase BREXAFEMME from wholesalers at the lower program price then remit us the difference between their acquisition cost and the lower program price, resulting in a reduction of product revenue. Accounts receivable is reduced for the estimated amount of unprocessed chargeback claims attributable to sale.
- Commercial Rebates – We contract with commercial payors such as insurers and PBMs and offer rebates for utilization and formulary status. These reserves are recorded in the same period in which the related revenue is recognized, resulting in a reduction of product revenue.

License Agreement Revenue

We have entered into arrangements involving the sale or license of intellectual property and the provision of other services. When entering into any arrangement involving the sale or license of intellectual property rights and other services, we determine whether the arrangement is subject to accounting guidance in ASC 606, Revenue from Contracts with Customers, as well as ASC 808, Collaborative Arrangements (Topic 808). If we determine that an arrangement includes goods or services that are central to our business operations for consideration, we will then identify the performance obligations in the contract using the unit-of-account guidance in Topic 606. For a distinct unit-of-account that is within the scope of Topic 606, we will apply all of the accounting requirements in Topic 606 to that unit-of-account, including the recognition, measurement, presentation and disclosure requirements. For a distinct unit-of-account that is not within the scope of Topic 606, we will recognize and measure the distinct unit-of-account based on other authoritative ASC Topics or on a reasonable, rational, and consistently applied policy election.

In arrangements that include the sale or license of intellectual property and other promised services, we first identify if the licenses are distinct from the other promises in the arrangement. If the license is not distinct, the license is combined with other services into a single performance obligation. For the sale of intellectual property that is distinct, fixed consideration and variable consideration are included in the transaction price and recognized in revenue immediately to the extent that it is probable that there would not be a significant reversal of cumulative revenue in the future. If the sale or license of intellectual property is not distinct, revenue is deferred and recognized over the estimated period of our combined performance obligation.

Research and Development Accruals

We are required to estimate our expenses resulting from our obligations under contracts with CROs, clinical site agreements, vendors, and consultants in connection with conducting ibrexafungerp clinical trials and preclinical studies and other development activities. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate development and trial expenses in our consolidated financial statements by matching those expenses with the period in which the services and efforts are expended by our service providers.

For clinical trials, we account for these expenses according to the progress of the trial as measured by actual hours expended by CRO personnel, investigator performance or completion of specific tasks, patient progression, or timing of various aspects of the trial. For preclinical development services performed by outside service providers, we determine accrual estimates through financial models, taking into account development progress data received from outside service providers and discussions with our knowledgeable internal personnel and service provider personnel. During the course of a clinical trial or preclinical study or development project, we adjust our rate of trial or project expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date within our consolidated financial

statements based on the facts and circumstances known to us at that time. Our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting changes in estimates in any particular period. We have not experienced any significant adjustments to our estimates to date.

Stock-Based Compensation

We record the fair value of stock options issued as of the grant date as compensation expense. We recognize compensation expense over the requisite service period, which is equal to the vesting period.

Stock-based compensation expense has been reported in our statements of operations as follows (dollars in thousands):

	Years Ended December 31,	
	2022	2021
Research and development	$ 1,076	$ 631
Selling, general and administrative	2,436	1,457
Total	$ 3,512	$ 2,088

On December 31, 2022, the aggregate intrinsic value of outstanding options to purchase shares of our common stock was zero, based upon the $1.56 closing sales price per share of our common stock as reported on the Nasdaq Global Market on that date.

Determination of the Fair Value of Stock-based Compensation Grants

We calculate the fair value of stock-based compensation arrangements using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of subjective assumptions, including volatility of our common stock, the expected term of our stock options, the risk free interest rate for a period that approximates the expected term of our stock options, and the fair value of the underlying common stock on the date of grant. In applying these assumptions, we considered the following factors:

- we estimate expected volatility based on the volatility of our own common stock trading history and implied volatility;
- the assumed dividend yield is based on our expectation of not paying dividends on our underlying common stock for the foreseeable future;
- we determine the average expected life of stock options based on the simplified method in accordance with SEC Staff Accounting Bulletin Nos. 107 and 110. We expect to use the simplified method until we have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term;
- we determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant; and
- we recognize forfeitures as they are incurred.

The assumptions used in the Black-Scholes option-pricing model for the years ended December 31, 2022 and 2021 are set forth below:

Employee Stock Options

	Years Ended December 31,	
	2022	2021
Weighted average risk-free interest rate	2.45%	0.64%
Weighted average expected term (in years)	6.04	5.15
Weighted average expected volatility	73.80%	62.10%

Non-Employee Stock Options

	Years Ended December 31,	
	2022	2021
Weighted average risk-free interest rate	3.18%	0.74%
Weighted average expected term (in years)	5.63	5.79
Weighted average expected volatility	74.20%	69.56%

Warrant Liabilities

We account for the outstanding warrants associated with the March 2018, December 2019, December 2020, and April 2022 public offerings as well as the Loan Agreement warrants associated with the remaining unfunded tranches as liabilities measured at fair value. The fair values of these warrants have been determined using the Black-Scholes valuation model. We determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities and utilize the remaining term of the warrant as the expected term. We estimate expected volatility using the historical volatility of our

common stock given we have sufficient history to support the expected terms of the warrants and implied volatility. See Note 2 to our consolidated financial statements on this Annual Report for further details.

Convertible Debt and Derivative Liabilities

For the convertible notes, we account for the bifurcated embedded conversion option, inclusive of the interest make-whole provision and make-whole fundamental change provision, as long-term derivative liabilities in our consolidated balance sheet. The derivative liabilities are remeasured at each reporting period using the binomial lattice model with changes in fair value recorded in the consolidated statements of operations in other (income) expense. We used the binomial lattice valuation model to value the derivative liabilities at inception and on subsequent valuation dates. This model incorporates transaction details such as stock price, contractual terms, dividend yield, risk-free rate, adjusted equity volatility, credit rating, market credit spread, and estimated yield. See Note 2 to our consolidated financial statements on this Annual Report for further details.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

This item is not applicable to smaller reporting companies.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of SCYNEXIS, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of SCYNEXIS, Inc. and subsidiaries (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, changes in stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred significant losses and negative cash flows from operations and has limited capital resources to fund ongoing operations which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Gross-to-net rebate accruals — Refer to "Note 2 – Summary of Significant Accounting Policies" and "Note 11 – Revenue" to the financial statements

Critical Audit Matter Description

As more fully disclosed in Note 2 and Note 11 of the financial statements, the Company's product revenue is recognized in accordance with Accounting Standards Codification Topic 606 ("ASC 606") upon the transfer of control of the Company's product to a customer and is measured as the amount of consideration the Company expects to receive in exchange for

transferring the product to a customer ("transaction price"). The transaction price for product sales is reduced by variable consideration related to certain gross-to-net ("GTN") adjustments, including chargebacks, rebates, discounts, incentives, and returns, and the Company will estimate the amount of this variable consideration that should be included in the transaction price using the expected value method. The amount of variable consideration that is included in the transaction price may be constrained and is included in net sales only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. These estimates take into consideration prescription demand from commercial providers, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns, and historical trends.

We identified management's estimation of certain GTN adjustments, specifically copay and commercial rebates ("GTN rebates") as a critical audit matter, given the complexity involved in determining the significant assumptions used in estimating the transaction price. Auditing these estimates involved especially subjective judgment and audit effort.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the accounting for the Company's GTN rebates included the following, among others:

- We evaluated management's significant accounting policies related to GTN rebates for reasonableness and consistency.
- We evaluated the appropriateness and consistency of the Company's methods and assumptions used to calculate GTN rebates.
- We tested the mathematical accuracy of GTN rebates.
- We tested the overall reasonableness of GTN rebates recorded at period end by developing an expectation for comparison to actual recorded balances.
- We tested GTN rebate claims processed by the Company, including evaluating those claims for consistency with the conditions and terms of the Company's contractual arrangements.

/s/ DELOITTE & TOUCHE LLP

Morristown, New Jersey
March 31, 2023

We have served as the Company's auditor since 2000.

SCYNEXIS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 45,814	$ 104,484
Short-term investments	27,689	—
Prepaid expenses and other current assets	2,503	3,569
Accounts receivable, net	2,101	861
Inventory, net	899	463
Restricted cash	55	—
Total current assets	79,061	109,377
Other assets	5,511	6,235
Deferred offering costs	73	150
Restricted cash	163	218
Intangible assets, net	408	1,056
Operating lease right-of-use asset (Note 9)	2,594	2,801
Total assets	**$ 87,810**	**$ 119,837**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,937	$ 7,848
Accrued expenses	5,628	5,698
Other liabilities, current portion (See Note 8)	5,771	—
Operating lease liability, current portion (Note 9)	282	70
Total current liabilities	17,618	13,616
Other liabilities	—	3,345
Warrant liabilities	18,644	18,062
Convertible debt and derivative liability (Note 8)	11,001	11,607
Loan payable (Note 8)	34,393	28,745
Operating lease liability (Note 9)	2,921	3,204
Total liabilities	84,577	78,579
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, authorized 5,000,000 shares as of December 31, 2022 and December 31, 2021; 0 shares issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value, 150,000,000 shares authorized as of December 31, 2022 and 100,000,000 shares as of December 31, 2021; 32,682,342 and 28,705,334 shares issued and outstanding as of December 31, 2022, and December 31, 2021, respectively	36	32
Additional paid-in capital	425,485	400,705
Accumulated deficit	(422,288)	(359,479)
Total stockholders' equity	3,233	41,258
Total liabilities and stockholders' equity	**$ 87,810**	**$ 119,837**

The accompanying notes are an integral part of the financial statements.

SCYNEXIS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Years Ended December 31,	
	2022	**2021**
Revenue:		
Product revenue, net	$ 4,988	$ 1,113
License agreement revenue	103	12,050
Total revenue	5,091	13,163
Operating expenses:		
Cost of product revenue	628	312
Research and development	27,259	23,773
Selling, general and administrative	62,961	49,916
Total operating expenses	90,848	74,001
Loss from operations	(85,757)	(60,838)
Other (income) expense:		
Loss on extinguishment of debt	—	2,725
Amortization of debt issuance costs and discount	1,589	1,303
Interest income	(1,415)	(24)
Interest expense	5,198	2,660
Other income	(3)	(13)
Warrant liabilities fair value adjustment	(22,301)	(30,365)
Derivative liability fair value adjustment	(1,316)	(1,170)
Total other income	(18,248)	(24,884)
Loss before taxes	(67,509)	(35,954)
Income tax benefit	4,700	3,088
Net loss	$ (62,809)	$ (32,866)
Net loss per share – basic and diluted	$ (1.47)	$ (1.25)
Weighted average common shares outstanding – basic and diluted	42,613,510	26,384,713

The accompanying notes are an integral part of the financial statements.

SCYNEXIS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Shares of Common Stock	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balances as of December 31, 2020	19,663,698	$ 20	$ 349,351	$ (326,613)	$ 22,758
Net loss	—	—	—	(32,866)	(32,866)
Stock-based compensation expense	—	—	2,088	—	2,088
Common stock issued through employee stock purchase and stock option plans	4,943	—	22	—	22
Common stock issued, net of expenses	8,067,562	11	41,029	—	41,040
Common stock issued for conversion of April 2020 Notes	959,080	1	7,452	—	7,453
Common stock issued for vested restricted stock units	10,051	—	(3)	—	(3)
Vested Loan Agreement warrants	—	—	766	—	766
Balances as of December 31, 2021	28,705,334	$ 32	$ 400,705	$ (359,479)	$ 41,258
Net loss	—	—	—	(62,809)	(62,809)
Stock-based compensation expense	—	—	3,685	—	3,685
Common stock issued through employee stock purchase and stock option plans	6,834	—	18	—	18
Common stock issued, net of expenses	3,895,943	4	21,006	—	21,010
Common stock issued for vested restricted stock units	74,231	—	—	—	—
Vested Loan Agreement warrants	—	—	71	—	71
Balances as of December 31, 2022	32,682,342	$ 36	$ 425,485	$ (422,288)	$ 3,233

The accompanying notes are an integral part of the financial statements.

SCYNEXIS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (62,809)	$ (32,866)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	606	379
Stock-based compensation expense	3,686	2,088
Accretion of investment discount	(309)	—
Amortization of debt issuance costs and discount	1,589	1,303
Change in fair value of warrant liabilities	(22,301)	(30,365)
Change in fair value of derivative liabilities	(1,316)	(1,170)
Noncash operating lease expense for right-of-use asset	207	198
Loss on extinguishment of debt	—	2,725
Changes in operating assets and liabilities:		
Prepaid expenses, other assets, deferred costs, and other	1,636	1,597
Accounts receivable	(1,240)	(861)
Inventory	(436)	(5,292)
Accounts payable	(1,481)	2,763
Accrued expenses, other liabilities, and other	2,285	4,941
Net cash used in operating activities	(79,883)	(54,560)
Cash flows from investing activities:		
Purchase of intangible assets	(9)	(1,172)
Purchase of investments	(27,380)	—
Net cash used in investing activities	(27,389)	(1,172)
Cash flows from financing activities:		
Proceeds from common stock issued	47,248	38,552
Payments of offering costs and underwriting discounts and commissions	(3,638)	(205)
Proceeds from loan payable	5,000	30,000
Payments of loan payable issuance costs	(26)	(1,253)
Proceeds from employee stock purchase plan issuances	18	22
Repurchase of shares to satisfy tax withholdings	—	4
Net cash provided by financing activities	48,602	67,120
Net (decrease) increase in cash, cash equivalents, and restricted cash	(58,670)	11,388
Cash, cash equivalents, and restricted cash at beginning of period	104,702	93,314
Cash, cash equivalents, and restricted cash at end of period	$ 46,032	$ 104,702
Supplemental cash flow information:		
Cash paid for interest	$ 5,190	$ 2,255
Cash received for interest	$ 1,106	$ 24
Noncash financing and investing activities:		
Purchased intangible assets included in accounts payable and accrued expenses	$ —	$ 78
Deferred offering and issuance costs included in accounts payable	$ —	$ 430
Deferred offering costs reclassified to additional paid-in capital	$ 77	$ 86
Common stock issued for settlement of senior convertible notes	$ —	$ 7,452
Reclass of warrant liability to additional paid in capital	$ 71	$ 298
Reclass of deferred asset associated with issuance of loan payable to debt discount	$ 206	$ 390
Settlement of liability for exercise of warrants	$ —	$ 3,091

The accompanying notes are an integral part of the financial statements.

1. Description of Business and Basis of Preparation

Organization

SCYNEXIS, Inc. (“SCYNEXIS” or the “Company”) is a Delaware corporation formed on November 4, 1999. SCYNEXIS is a biotechnology company, headquartered in Jersey City, New Jersey, and is pioneering innovative medicines to overcome and prevent difficult-to-treat and drug-resistant infections. The Company is developing its lead product candidate, ibrexafungerp, as a broad-spectrum, intravenous (“IV”)/oral agent for severe, hospital-based indications. In June 2021, the U.S. Food and Drug Administration (“FDA”) approved BREXAFEMME® (ibrexafungerp tablets) for treatment of patients with vulvovaginal candidiasis (“VVC”), also known as vaginal yeast infection. In December 2022, the Company announced that the FDA approved a second indication for BREXAFEMME for the reduction in the incidence of recurrent vulvovaginal candidiasis ("RVVC").

In October 2022, the Company announced that it was actively pursuing a U.S. commercialization partner to out-license BREXAFEMME in order to refocus its resources on the clinical development of ibrexafungerp for severe, hospital-based indications. As a result, the Company has wound down its promotional activities associated with BREXAFEMME, while keeping BREXAFEMME on the market and available to patients, and has ceased actively promoting BREXAFEMME. Additionally, the Company concluded the partnership with its contracted commercial sales partner, Amplity Health ("Amplity"), on November 30, 2022, and the Company undertook a workforce reduction.

In March 2023, the Company entered into a license agreement (the "License Agreement") with GlaxoSmithKline Intellectual Property (No. 3) Limited ("GSK"), subject to customary closing conditions, in which the Company granted GSK an exclusive (even as to the Company and its affiliates), royalty-bearing, sublicensable license for the development and commercialization of ibrexafungerp, including the approved product BREXAFEMME, for all indications, in all countries other than Greater China and certain other countries already licensed to third parties (See Note 16).

The Company is party to a Loan and Security Agreement, dated May 13, 2021, with Hercules Capital, Inc. ("Hercules Capital") and Silicon Valley Bridge Bank, N.A. (“SVB”) (the Loan Agreement), pursuant to which Hercules Capital, SVB and each of the other lenders from time-to-time party to the Loan Agreement (collectively, the “Lenders”) loaned to the Company $35 million as of December 31, 2022.

In connection with the entering into of the License Agreement, the Company entered into a First Amendment and Consent to Loan and Security Agreement with the Lenders pursuant to the Lenders consented to the Company entering into the License Agreement and the Company agreed to pay to the Lenders an amount equal to the sum of (i) all outstanding principal plus all accrued and unpaid interest with respect to the amounts loaned under the Loan Agreement, (ii) the prepayment fee payable under Loan Agreement (approximately $0.3 million), (iii) the final payment payable under Loan Agreement (approximately $1.4 million), and (iv) all other sums, if any, that shall have become due and payable with respect to loan advances under the Loan Agreement. These payments by the Company will become due upon the earliest of (A) one business day following receipt by the Company of the $90 million upfront payment payable to the Company under the License Agreement, (B) June 1, 2023, or (C) the termination of the License Agreement.

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. Intercompany balances and transactions are eliminated in consolidation.

Liquidity and Going Concern

The Company has funded its operations primarily through a combination of net proceeds from equity offerings, debt financings, and other non-dilutive third-party funding (e.g., grants), strategic alliances and licensing arrangements. To date, the Company has generated minimal revenue from product sales. The Company does not know if or when the Company will be able to generate significant revenue from product sales. In addition, the Company expects to incur expenses in connection with the Company's ongoing development activities, particularly as the Company continues the research, development and clinical trials of, and seek regulatory approval for, its product candidates. The Company anticipates that it will need substantial additional funding in connection with its continuing future operations.

As of the date the accompanying consolidated financial statements were issued (the “issuance date”), management evaluated the significance of the following negative financial conditions in accordance with ASC 205-40, *Going Concern*:

- The Company has incurred recurring losses since its inception, including net losses of $62.8 million and $32.9 million for the years ended December 31, 2022 and 2021, respectively. In addition, as of December 31, 2022, the Company had an accumulated deficit of $422.3 million. The Company expects to continue to generate operating losses for the foreseeable future.

- As of December 31, 2022, the Company had approximately $73.5 million of unrestricted cash, cash equivalents and short-term investments available to fund the Company's operations.
- The Company expects to incur substantial expenditures to fund its operations and ongoing development activities for the foreseeable future. In order to fund its operations and ongoing development activities, the Company will need to secure additional sources of outside capital. As noted above and as further disclosed in Note 16, the Company entered into a License Agreement with GSK in March 2023, in which the Company granted GSK with an exclusive license for the development and commercialization of ibrexafungerp, including the approved product BREXAFEMME. The closing of the License Agreement is subject to the satisfaction of customary closing conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and therefore the related cash flows, including the upfront payment of $90 million, were not included in the Company's ASC 205-40 analysis as of the issuance date. Management expects the License Agreement to close during the second quarter of 2023.
- In the event the License Agreement does not close, the Company may be unable to meet its obligations as they become due over the next twelve months beyond the issuance date. In that regard, management will be required to seek other strategic alternatives, which may include, raising additional capital through equity offerings, including utilizing our existing facility, debt financings, or other non-dilutive third-party funding. While the Company has a history of successfully raising capital in this manner, management can provide no assurance that additional capital will be secured or on terms that are acceptable to the Company. In the event the Company is unable to secure additional capital, management will be required to seek other strategic alternatives, which may include, among others, delaying expenditures, reducing the scope of its research and development programs, significant changes to its operating plan, a sale of certain of the Company's assets, a sale of the entire Company to strategic or financial investors, and/or allowing the Company to become insolvent by filing for bankruptcy.
- As disclosed in Note 8, the Company is required to maintain compliance with certain covenants prescribed by the Term Loan. The first covenant pertains to a minimum cash requirement whereby the Company must maintain a minimum amount of unrestricted and unencumbered cash in accounts with the lender at all times that represents at least 50% of the outstanding principal on the Term Loan (the "minimum cash"). In the event the minimum cash is not maintained, the second covenant requires the Company to maintain compliance with a trailing three-month net product revenue threshold (the "revenue covenant"). As of December 31, 2022 and through the issuance date, the Company met the minimum cash requirement. However, management can provide no assurance that the minimum cash will be maintained for at least twelve months beyond the issuance date. If the Company does not meet the minimum cash requirement and, as such, must maintain compliance with the revenue covenant, management does not expect the Company will be able to comply with the revenue covenant for any period over the next twelve months beyond the issuance date. If the Company is required to comply with, but does not maintain compliance with, the revenue covenant, management may seek a waiver from the lender or refinance the outstanding borrowings under the Term Loan with another lender. However, management can provide no assurance a waiver will be granted by the lender or on terms that are acceptable to the Company. Similarly, management can provide no assurance that the Company will be able to refinance the amounts outstanding on the Term Loan or obtain a new loan on terms that are acceptable to the Company. In the event a waiver is not granted, or the Term Loan is not refinanced, the lender may exercise any and all of its rights and remedies provided for under the borrowing agreement which may include, among others, entering into a forbearance agreement, demanding payment, and/or seizing the underlying assets secured by the Term Loan.
- Further, as noted above, the Company entered into an amendment to the Loan Agreement in March 2023, which amends the original terms of the Loan Agreement to require that the outstanding principal and accrued and unpaid interest amounts, the prepayment fee and the final payment will become due and payable at the earliest of (A) one business day following receipt by the Company of the upfront payment payable to the Company under the License Agreement, (B) June 1, 2023, or (C) the termination of the License Agreement. While management expects that the License Agreement will close during the second quarter of 2023, if the License Agreement were unable to close or were to close at a later date than originally expected, the amendment to the Loan agreement would require the Company to repay the amounts due under the Loan Agreement potentially prior to the close of the License Agreement.

These uncertainties raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on the basis that the Company will continue to operate as a going concern, which contemplates that the Company will be able to realize assets and settle liabilities and commitments in the normal course of business for twelve months following the issuance date. Accordingly, the accompanying consolidated financial statements do not include any adjustments that may result from the outcome of these uncertainties.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates and judgments include: revenue recognition including gross to net estimates and the identification of performance obligations in licensing arrangements; determination of the fair value of stock-based compensation grants; the estimate of services and effort expended by third-party research and development service providers used to recognize research and development expense; and the estimates and assumptions utilized in measuring the fair values of the warrant and derivative liabilities each reporting period.

2. Summary of Significant Accounting Policies

Concentration of Credit Risk

Financial instruments, which potentially expose the Company to concentrations of credit risk, consist principally of cash on deposit, cash equivalents, short-term investments, and accounts receivable. The Company's money market fund investment (recognized as cash and cash equivalents) and short-term investments are with what the Company believes to be high quality issuers. The Company has not experienced any significant losses in such accounts. See Note 11 for concentrations of credit risk associated with the Company's accounts receivable and revenue with customers.

As of December 31, 2022, the Company held cash, cash equivalents, and short-term investments at Silicon Valley Bank ("SVB"). On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation ("FDIC") was appointed as receiver. As of the closure of SVB on March 10, 2023, the Company held approximately $0.3 million in cash on deposit and approximately $7.0 million in a money market account with SVB who was administering the account as our agent. The Company's remaining cash, cash equivalents and short-term investments are primarily held in a money market account and in U.S. treasury securities that are unaffiliated with SVB and held with another financial institution acting as custodian, but which SVB administers on the Company's behalf. The Company is able to access all cash, cash equivalents and short-term investments held at or through SVB and at our financial institution custodians. The Company has not experienced any losses in such accounts.

Cash and Cash Equivalents

The Company considers any highly liquid investments with a remaining maturity of three months or less when purchased to be cash and cash equivalents. The Company reported cash, cash equivalents, and restricted cash of $46.0 million and $104.7 million as of December 31, 2022 and 2021, respectively. See Note 9 for further details on the nature of the restricted cash.

Short-Term Investments

The Company's held-to-maturity short-term investments in U.S. government securities are carried at amortized cost and any premiums or discounts are amortized or accreted through the maturity date of the investment. Any impairment that is not deemed to be temporary is recognized in the period identified.

Accounts Receivable, Net

Accounts receivable are reported on the accompanying consolidated balance sheet at outstanding amounts due from customers for product sales net of discounts, chargebacks, and wholesaler distribution fees. The Company evaluates the collectability of accounts receivable on a regular basis, by reviewing the financial condition and payment history of its customers, an overall review of collections experience on other accounts, and economic factors or events expected to affect future collections experience. An allowance for doubtful accounts is recorded when a receivable is deemed to be uncollectible. The Company did not record an allowance for doubtful accounts as of December 31, 2022.

Inventory, Net

Inventory is stated at the lower of cost or net realizable value. Inventory on the accompanying balance sheet includes costs related to the raw material, third party manufacturing, and packaging for BREXAFEMME. Raw material inventory includes the costs associated with the manufacture of ibrexafungerp, the active product ingredient in BREXAFEMME. Work in process inventory includes the costs necessary to package ibrexafungerp into BREXAFEMME, at which point the inventory is then released for commercial use and considered a finished good that is available to be sold. Inventory that is not expected to be sold within one year of the reporting period is classified as long term in other assets on the consolidated balance sheet. Prior to the regulatory approval of an investigational drug, the Company recognizes as research and development expense costs related to the manufacture of an investigational drug when incurred. Upon regulatory approval, the Company begins capitalizing such production and manufacturing expenses as inventory. For BREXAFEMME, capitalization of costs as inventory began upon regulatory approval on June 1, 2021.

Revenue Recognition

The Company accounts for revenue in accordance with Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("Topic 606"). Under ASC Topic 606, an entity recognizes revenue when its customer obtains control of goods and services, in an amount that reflects the consideration that the entity expects to be entitled in exchange for those goods and services. The Company performs the following five steps to recognize revenue under ASC Topic 606: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only recognizes revenue when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that will be transferred to the customer.

Product Revenue, Net

The Company sells BREXAFEMME primarily to wholesalers in the United States and are initially invoiced at contractual list prices. These wholesalers subsequently resell BREXAFEMME to specialty and other retail pharmacies. In addition to agreements with the wholesalers, the Company enters into arrangements with third-party payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks, and discounts for the purchase of BREXAFEMME. The transaction price for product sales is reduced by variable consideration related to certain gross to net ("GTN") adjustments, including chargebacks, rebates, discounts, incentives, and returns, and the Company will estimate the amount of this variable consideration that should be included in the transaction price using the expected value method.

Specific considerations around the Company's product revenue gross to net GTN adjustments are as follows:

- Voluntary Patient Assistance Programs – Through vendors, the Company offers copay assistance to provide financial assistance to patients for the portion of their prescription cost that is not covered by payors. The reduction in product revenue due to the copay programs is based on an estimate of claims and costs per claim that the Company expects to receive associated with product revenue that has been recognized. This includes potential product revenue that remains in the distribution channel at the end of a reporting period.
- Trade Discounts and Wholesaler Fees – The Company offers discounts and pays certain distributor service fees. These are recorded as a reduction in product revenue based on distributors' purchases and the applicable discount rate.
- Product Stocking Fees – During the initial launch of BREXAFEMME, the Company offered additional fees to wholesalers and certain indirect customers to incent stocking at wholesalers and pharmacies. These were recorded as a reduction in product revenue based on these customer's purchases during the eligible period and limited to a certain volume.
- Product Returns - Generally, the Company's customers have the right to return products during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. Since the Company has a limited history of BREXAFEMME returns, the Company estimated returns based on industry data for comparable products in the market. As the Company distributes its product and establishes historical sales over a longer period of time (i.e., two to three years), the Company will be able to place more reliance on historical purchasing, demand and return patterns of its customers when evaluating its reserves for product returns. BREXAFEMME has a thirty-month shelf life.
- Chargebacks - For certain entities, pricing on BREXAFEMME is extended below wholesaler list price. Entities that purchase BREXAFEMME from wholesalers at the lower program price then remit the Company the difference between their acquisition cost and the lower program price, resulting in a reduction of product revenue. Accounts receivable is reduced for the estimated amount of unprocessed chargeback claims attributable to sale.
- Commercial Rebates – The Company contracts with commercial payors such as insurers and PBMs and offer rebates for utilization and formulary status. These reserves are recorded in the same period in which the related revenue is recognized, resulting in a reduction of product revenue.
- Government Rebates – The Company is subject to discount obligations under state Medicaid programs, Medicare, and other government programs. Provisions for government rebates are based on the estimated amount of rebates and incentives to be claimed on the related sales from the period. These reserves are recorded in the same period in which the related revenue is recognized, resulting in a reduction of product revenue. For Medicare, the Company must also estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program.

The Company determined that performance obligations are satisfied and product revenue is recognized when a customer takes control of the Company's product, which occurs at a point in time. This occurs upon delivery of the BREXAFEMME to customers, at which point the Company recognizes revenue. Payment is typically received 70 to 90 days after satisfaction of the Company's performance obligations.

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products to a customer ("transaction price"). The transaction price for product sales is reduced by variable consideration related to chargebacks, rebates, discounts, incentives, and returns. The Company will estimate the amount of variable consideration that should be included in the transaction price using the expected value method. These estimates take into consideration prescription demand from commercial providers, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns, and historical trends. These provisions reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in net sales only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. Sales commissions and other incremental costs of obtaining customer contracts are expensed as incurred as the amortization periods would be less than one year.

License Agreement Revenue

The Company has entered into arrangements involving the sale or license of intellectual property and the provision of other services. When entering into any arrangement involving the sale or license of intellectual property rights and other services, the Company determines whether the arrangement is subject to accounting guidance in ASC 606, *Revenue from Contracts with Customers*, as well as ASC 808, *Collaborative Arrangements* ("Topic 808"). If the Company determines that an arrangement includes goods or services that are central to the Company's business operations for consideration, the Company will then identify the performance obligations in the contract using the unit of account guidance in Topic 606. For a distinct unit of account that is within the scope of Topic 606, the Company applies all of the accounting requirements in Topic 606 to that unit of account, including the recognition, measurement, presentation and disclosure requirements. For a distinct unit of account that is not within the scope of Topic 606, the Company will recognize and measure the distinct unit of account based on other authoritative ASC Topics or on a reasonable, rational, and consistently applied policy election.

Analyzing the arrangement to identify performance obligations requires the use of judgment. In arrangements that include the sale or license of intellectual property and other promised services, the Company first identifies if the licenses are distinct from the other promises in the arrangement. If the license is not distinct, the license is combined with other services into a single performance obligation. Factors that are considered in evaluating whether a license is distinct from other promised services include, for example, whether the counterparty can benefit from the license without the promised service on its own or with other readily available resources and whether the promised service is expected to significantly modify or customize the intellectual property.

The Company classifies non-refundable upfront payments, milestone payments and royalties received for the sale or license of intellectual property as revenues within its statements of operations because the Company views such activities as being central to its business operations. For the sale of intellectual property that is distinct, fixed consideration and variable consideration are included in the transaction price and recognized in revenue immediately to the extent that it is probable that there would not be a significant reversal of cumulative revenue in the future. For the license of intellectual property that is distinct, fixed and variable consideration (to the extent there will not be a significant reversal in the future) are also recognized immediately in income, except for consideration received in the form of royalty or sales-based milestones, which is recorded when the customer's subsequent sales or usages occur. If the sale or license of intellectual property is not distinct, revenue is deferred and recognized over the estimated period of the Company's combined performance obligation. For contractual arrangements that meet the definition of a collaborative arrangement under Topic 808, consideration received for any units-of-account that are outside the scope of Topic 606 are recognized in the statements of operations by considering (i) the nature of the arrangement, (ii) the nature of the Company's business operations, and (iii) the contractual terms of the arrangement.

Cost of Product Revenues

The cost of product revenues consists primarily of distribution, freight costs, royalty costs, and other manufacturing costs. Prior to the regulatory approval of BREXAFEMME on June 1, 2021, the Company expensed as research and development the costs associated with the third-party manufacture of BREXAFEMME.

Warrant Liabilities

The Company accounts for the warrants associated with the March 2018 public offering, December 2019 public offering, December 2020 public offering, and April 2022 public offering and remaining warrants under the Loan Agreement as liabilities measured at fair value. The fair values of these warrants have been determined using the Black-Scholes valuation model ("Black-Scholes"). The warrants are subject to remeasurement at each balance sheet date, using Black-Scholes, with any changes in the fair value of the outstanding warrants recognized in the accompanying consolidated statements of operations.

Loan Payable

The Company initially reviews loan payables to identify the units of account for recognition purposes. The Company identifies the units of account by identifying each freestanding financial instrument included in the debt arrangement. For freestanding equity-linked financial instruments that are not in the form of shares, liability classification is used if the instrument embodies an obligation to repurchase the Company's shares that may require the use of cash or other assets or the instrument may require the issuance of a variable number of the Company's shares with a monetary value that is predominately based on a fixed value, based on variations in variables other than the fair value of the Company's stock, or based on variations inversely related to the fair value of the Company's stock. The Company will then review for embedded features within the debt instrument to evaluate whether the embedded features require bifurcation from the debt host instrument. Embedded features typically include conversion or exchange features, redemption features, or other embedded features. The identified embedded feature is bifurcated from the debt host instrument if the criteria in ASC 815-15-25-1 are met. Debt arrangements are classified on the consolidated balance sheet as current if the obligation of the debt arrangement is reasonably expected to be liquidated within twelve months. The Company's loan payable is recorded net of debt discount which comprised issuance costs, customary closing and final fees, and the fair value of the additional warrants issued in conjunction with the loan payable. See Note 8 for further details.

Convertible Debt and Derivative Liability

In connection with the Company's issuance of its March 2019 6.0% Convertible Senior Notes (the "March 2019 Notes"), the Company bifurcated the embedded conversion option, inclusive of the interest make-whole provision and make-whole fundamental change provision, and recorded the embedded conversion option as a long-term derivative liability in the Company's balance sheet in accordance with FASB ASC 815, *Derivatives and Hedging*. The convertible debt and the derivative liability associated with the March 2019 Notes is presented in total on the consolidated balance sheet as the convertible debt and derivative liability. The convertible debt is carried at amortized cost. The derivative liability will be remeasured at each reporting period using the binomial lattice model with changes in fair value recorded in the consolidated statements of operations in other expense (income). See Note 8 and 14 for further details.

Research and Development

Major components of research and development costs include clinical trial activities and services, including related drug formulation, manufacturing, and other development, preclinical studies, cash compensation, stock-based compensation, fees paid to consultants and other entities that conduct certain research and development activities on the Company's behalf, materials and supplies, legal services, and regulatory compliance.

The Company is required to estimate its expenses resulting from its obligations under contracts with clinical research organizations, clinical site agreements, vendors, and consultants in connection with conducting ibrexafungerp clinical trials and preclinical development. The financial terms of these contracts are subject to negotiations which vary from contract to contract, and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company's objective is to reflect the appropriate development and trial expenses in its consolidated financial statements by matching those expenses with the period in which the services and efforts are expended. For clinical trials, the Company accounts for these expenses according to the progress of the trial as measured by actual hours expended by CRO personnel, investigator performance or completion of specific tasks, patient progression, or timing of various aspects of the trial. For preclinical development services performed by outside service providers, the Company determines accrual estimates through financial models, taking into account development progress data received from outside service providers and discussions with applicable Company and service provider personnel.

Patent Expenses

Costs related to filing and pursuing patent applications, as well as costs related to maintaining the Company's existing patent portfolio, are recorded as expense as incurred since recoverability of such expenditures is uncertain.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on the Company's principal or, in absence of a principal, most advantageous market for the specific asset or liability.

The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to

their initial measurement. The hierarchy requires the Company to use observable inputs when available, and to minimize the use of unobservable inputs when determining fair value. The three tiers are defined as follows:

- Level 1 — Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2 — Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities; and
- Level 3 — Unobservable inputs that are supported by little or no market data, which require the Company to develop its own assumptions about the assumptions market participants would use in pricing the asset or liability based on the best information available in the circumstances.

Amortization of Debt Issuance Costs and Discount

The Company's convertible debt is recorded net of debt issuance costs and discount which comprised issuance costs and an advisory fee, and the discount initially recognized for the fair value of the bifurcated derivative liability. The portion of the debt issuance costs allocated to the convertible debt, based on the amount of proceeds allocated between the convertible debt and the derivative liability, is being amortized over the term of the convertible debt using the effective interest method in addition to the discount initially recognized for the fair value of the bifurcated derivative liability from the convertible debt. The Company's loan payable was recorded net of debt discount which comprised issuance costs, customary closing and final fees, and the fair value of the warrants issued in conjunction with the loan payable. The resulting debt discount is being amortized over the term of the loan payable using the effective interest method. The amortization of debt issuance costs and discount is included in other expense within the accompanying consolidated statements of operations.

Income Taxes

The Company provides for deferred income taxes under the asset and liability method, whereby deferred income taxes result from temporary differences between the tax bases of assets and liabilities and their reported amounts in the consolidated financial statements. Valuation allowances are established when necessary to reduce deferred tax assets to the amount that the Company believes is more likely than not to be realized. The Company recognizes uncertain tax positions when the positions will be more likely than not sustained based solely upon the technical merits of the positions.

Stock-Based Compensation

The Company measures and recognizes compensation expense for all stock-based payment awards made to employees, officers, directors, and non-employees based on the estimated fair values of the awards as of grant date. The Company values equity instruments and stock options granted to employees and non-employees using the Black-Scholes valuation model. The value of the portion of the award that is ultimately expected to vest is recorded as expense over the requisite service periods. The Company recognize forfeitures as they are incurred.

Basic and Diluted Net Loss per Share of Common Stock

The Company calculates net loss per common share in accordance with ASC 260, *Earnings Per Share*. Basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Per ASC 260, *Earnings Per Share*, the weighted average number of common shares outstanding utilized for determining the basic net loss per common share for the year ended December 31, 2022 includes the outstanding prefunded warrants to purchase 11,666,667 and 3,200,000 shares of common stock issued in the April 2022 Public Offering and December 2020 public offering, respectively. The weighted average number of common shares outstanding utilized for determining the basic net loss per common share for the year ended December 31, 2021 includes the outstanding prefunded warrants to purchase 3,200,000 shares of common stock issued in the December 2020 public offering.

The following potentially dilutive shares of common stock have not been included in the computation of diluted net loss per share for all periods as the result would be anti-dilutive:

	December 31,	
	2022	2021
Outstanding stock options	1,740,308	1,542,126
Outstanding restricted stock units	633,270	133,834
Warrants to purchase common stock associated with March 2018 public offering - Series 2	798,810	798,810
Warrants to purchase common stock associated with December 2020 public offering - Series 2	6,800,000	6,800,000
Warrants to purchase common stock associated with April 2022 Public Offering	15,000,000	—
Common stock associated with the March 2019 Notes	1,138,200	1,138,200
Warrants to purchase common stock associated with Loan Agreement	198,811	170,410
Warrants to purchase common stock associated with Danforth	50,000	50,000
Total	26,359,399	10,633,380

Segment and Geographic Information

Operating segments are defined as components of an enterprise (business activity from which it earns revenue and incurs expenses) about which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker ("CODM") is the Chief Executive Officer. The CODM reviews consolidated operating results to make decisions about allocating resources and assessing performance for the entire Company. The Company views its operations and manages its business as one operating segment. The material assets of the Company were held in the United States for the years ended December 31, 2022 and 2021. In July 2019, the Company incorporated SCYNEXIS Pacific Pty Ltd, a wholly-owned subsidiary, in Sydney, Australia, for the initial purpose of conducting certain clinical trials and other research and development activities.

Although all operations are primarily based in the United States, the Company generated a portion of its revenue from the license agreement with Hansoh located outside of the United States for the years ended December 31, 2022 and 2021. All sales, including sales outside of the United States, are denominated in United States dollars.

Reclassification of Prior Year Amounts

Certain prior year amounts have been reclassified for consistency with the current year presentation.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The amendments in ASU 2016-13 require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. In November 2019, the FASB issued ASU No. 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)* ("ASU 2019-10"), which revised the effective dates for ASU 2016-13 for public business entities that meet the SEC definition of a smaller reporting company to fiscal years, and interim periods within those fiscal years, beginning after December 15, 2022, with early adoption permitted. The Company does not believe that ASU 2016-13 will have a material impact on its consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options and Derivatives and Hedging—Contracts in Entity's Own Equity: Accounting for Convertible Instruments and Contracts in and Entity's Own Equity* ("ASU 2020-06"). The amendments in ASU 2020-06 reduce the number of accounting models for convertible debt instruments and revises certain guidance relating to the derivative scope exception and earnings per share. The amendments in ASU 2020-06 are effective for public business entities that meet the definition of a SEC filer and a smaller reporting company for fiscal years beginning after December 15, 2023, and interim periods within those years. As a smaller reporting company, the Company is currently evaluating the impact ASU 2020-06 will have on its consolidated financial statements.

3. Short-term Investments

Short-term investments consisted of the following (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
As of December 31, 2022				
U.S. government securities	$ 27,689	$ —	$ (160)	$ 27,529
Total short-term investments	$ 27,689	$ —	$ (160)	$ 27,529

The Company's evaluated the unrealized loss position in U.S. government securities as of the balance sheet date and did not consider it to be indicative of an other-than-temporary impairment as the securities are highly-rated and the Company expects to realize the full principal amount at maturity.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2022	2021
Prepaid research and development services	$ 635	$ 247
Prepaid insurance	622	505
Other prepaid expenses	1,184	2,813
Other current assets	62	4
Total prepaid expenses and other current assets	$ 2,503	$ 3,569

5. Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2022	2021
Raw materials	$ 5,093	$ 5,162
Work in process	610	3
Finished goods	24	127
Total inventory	$ 5,727	$ 5,292

As of December 31, 2022, the Company's inventory consisted of $4.9 million of raw material that is not expected to be sold in one year and is classified as long term within other assets on the consolidated balance sheet.

6. Intangible Assets

Intangible assets consisted of the following (in thousands):

	December 31,	
	2022	2021
Intangible assets	$ 1,282	$ 1,250
Less: accumulated amortization	(874)	(194)
Total intangible assets, net	$ 408	$ 1,056

For the years ended December 31, 2022 and 2021, the Company recognized $0.7 million and $0.2 million in amortization expense, respectively. Intangible assets consist primarily of software implementation costs purchased in 2021 and are

amortized over a useful life of three years. The estimated remaining amortization expense of $0.4 million will be recognized in 2023.

7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued research and development expenses	$ 786	$ 1,498
Accrued employee bonus compensation	1,628	2,012
Other accrued expenses	1,313	1,078
Accrued severance	688	—
Accrued co-pay rebates	595	836
Accrued other rebates	618	274
Total accrued expenses	$ 5,628	$ 5,698

8. Borrowings

Loan Agreement

On May 13, 2021, the Company entered into the loan and security agreement ("Loan Agreement") with Hercules Capital, Inc. ("Hercules"), as administrative agent and collateral agent and a lender, and Silicon Valley Bank ("SVB"), for an aggregate principal amount of $60.0 million (the "Term Loan"). Pursuant to the Loan Agreement, the Term Loan is available to the Company in four tranches, subject to certain terms and conditions.

Under the terms of the Loan Agreement, the Company received an initial tranche of $20.0 million from the Lenders on the closing date. The second tranche of the Term Loan, consisting of up to an additional $10.0 million, became available to the Company upon receipt of approval from the FDA of ibrexafungerp for the treatment of vaginal yeast infections (the "First Performance Milestone") and was funded in June 2021. The third tranche of the Term Loan, consisting of an additional $5.0 million, was available to the Company upon (a) the First Performance Milestone and (b) the achievement of the primary endpoint from the Phase 3 study of ibrexafungerp in patients with recurrent VVC, and was funded in March 2022. The fourth tranche of the Term Loan, consisting of up to an additional $25.0 million, will be available to the Company from January 1, 2022 through December 31, 2023 in $5.0 million increments, subject to certain terms and conditions, including in maintaining a ratio of total outstanding Term Loan principal to net product revenues for BREXAFEMME below a certain specified level for a given draw period. The Company estimated the fair value of the loan payable using a credit spread valuation model and Level 3 inputs which included an implied secured spread, risk free rate, and secured yield of 9.84%, 4.37%, and 14.21%, respectively. At December 31, 2022, the fair value of the loan payable is $34.4 million.

The Term Loan will mature on March 3, 2025 (the "Maturity Date"); provided that, the Maturity Date shall be automatically extended to May 1, 2025 subject to the occurrence of certain conditions set forth in the Loan Agreement. The Term Loan bears interest at a variable annual rate equal to the greater of (a) 9.05% and (b) the Prime Rate (as reported in the Wall Street Journal) plus 5.80% (the "Interest Rate"). The Company may make payments of interest only through November 1, 2023, which may be extended to May 1, 2024 upon the achievement of the First Performance Milestone prior to November 1, 2023, and which is further extendable in quarterly increments until the Maturity Date, subject to continued compliance with the financial covenant of the Loan Agreement (the "interest-only period"). After the interest-only period, the principal balance and related interest will be required to be repaid in equal monthly installments and continuing until the Maturity Date.

In connection with the entry into the Loan Agreement, the Company issued to each of Hercules and SVB a warrant (collectively, the "Warrants") to purchase shares of the Company's common stock, par value $0.001 per share (the "Shares"). The amount of shares that may be purchased for the Warrants, collectively between Hercules and SVB, will not exceed 0.04 multiplied by the aggregate amount of the term loan advance, divided by the exercise price of the Warrants.

The Loan Agreement contains customary closing fees, prepayment fees and provisions, events of default, and representations, warranties and covenants, including a financial covenant requiring the Company to maintain certain levels of trailing three-month net product revenue solely from the sale of ibrexafungerp commencing on June 30, 2022. The financial covenant will be waived at any time in which the Company maintains unrestricted and unencumbered cash in accounts maintained with SVB and another financial institution equal to at least 50.0% of the total outstanding Term Loan principal amount, subject to certain requirements. Subject to certain exceptions, the Company's obligations under the Loan Agreement are secured by a first priority security interest on substantially all of the Company's personal property, other than intellectual property. The final closing fee of $1.4 million is recognized as a debt discount and is being accreted into the amortization of debt issuance costs and discount using the effective interest rate method over the term of the loan payable.

The initial Loan Agreement tranche of $20.0 million, the funding of the additional Term Loan tranches, the initial warrants and the additional warrants, were identified as freestanding instruments that were legally detachable and separately exercisable from each other. At the closing of the Loan Agreement, the Company issued 113,607 of warrants to purchase shares of the Company's common stock and recognized the initial warrants at their relative fair value of $0.5 million in shareholder's equity. In accordance with ASC 815-40, the additional remaining warrants to purchase shares of the Company's common stock at the closing of the Loan Agreement were recognized at their fair value as warrant liabilities given the variable settlement amount of the warrant shares. The additional remaining warrants under the Loan Agreement are considered an outstanding instrument at close of the Loan Agreement. The additional remaining warrants will vest and become exercisable upon the funding of the remaining term loan tranches available under the Loan Agreement and the amount of additional warrants will not exceed 0.04 multiplied by the aggregate amount of the term loan tranche, divided by the exercise price of the Warrants. The fair value of the initial warrant liabilities of approximately $0.7 million was recorded as a deferred asset and is reclassified to debt discount proportionately upon the funding of a Term Loan tranche. Upon the funding of the $10.0 million and $5.0 million for the second and third tranches in June 2021 and March 2022, the associated warrant liabilities of $0.3 million and $0.1 million were reclassed to additional paid in capital at settlement and 56,803 and 28,401 of warrants to purchase shares of the Company's common stock vested, respectively.

Future principal debt payments on the currently outstanding loan payable as of December 31, 2022 are as follows (in thousands):

2024	23,562
2025	11,438
Total principal payments	35,000
Final fee due at maturity	1,383
Total principal and final fee payment	36,383
Unamortized discount and debt issuance costs	(1,990)
Less current portion	—
Loan payable, long term	$ 34,393

April 2020 Note Purchase Agreement

On April 9, 2020, the Company entered into the April 2020 note purchase agreement with Puissance Life Science Opportunities Fund VI ("Puissance") and issued and sold to Puissance $10.0 million aggregate principal amount of its April 2020 6.0% Convertible Senior Notes (the "April 2020 Notes"), resulting in net proceeds of approximately $9.5 million after deducting $0.5 million for an advisory fee and other issuance costs.

In January 2021, Puissance converted the remaining $6.0 million of the April 2020 Notes for 959,080 shares of common stock. Upon conversion of the $6.0 million of the April 2020 Notes, the Company recognized a $2.7 million extinguishment loss which represents the difference between the total net carrying amount of the convertible debt and derivative liability of $4.8 million and the fair value of the consideration issued of $7.5 million.

March 2019 Note Purchase Agreement

On March 7, 2019, the Company entered into a Senior Convertible Note Purchase Agreement (the "March 2019 Note Purchase Agreement") with Puissance. Pursuant to the March 2019 Note Purchase Agreement, on March 7, 2019, the Company issued and sold to Puissance $16.0 million aggregate principal amount of its March 2019 Notes, resulting in $14.7 million in net proceeds after deducting $1.3 million for an advisory fee and other issuance costs.

As of December 31, 2022 and 2021, the Company's March 2019 Notes consists of the convertible debt balance of $11.0 million and $10.2 million, both presented net of the unamortized debt issuance costs allocated to the convertible debt of $0.3 million, and the bifurcated embedded conversion option derivative liability of $42,000 and $1.4 million, respectively. In connection with the Company's issuance of its March 2019 Notes, the Company bifurcated the embedded conversion option, inclusive of the interest make-whole provision and make-whole fundamental change provision, and recorded the embedded conversion option as a long-term derivative liability in the Company's balance sheet in accordance with ASC 815, *Derivatives and Hedging*, at its initial fair value of $7.0 million as the interest make-whole provision is settled in shares of common stock. For both the years ended December 31, 2022 and 2021, the Company recognized gains of $1.3 million on the fair value adjustment for the derivative liability. For the years ended December 31, 2022 and 2021, the Company recognized $0.7 million and $0.9 million, respectively, in amortization of debt issuance costs and discount, related to the March 2019 Notes.

The Company estimated the fair value of the convertible debt and derivative liability for the March 2019 Notes using a binomial lattice valuation model and Level 3 inputs. At December 31, 2022 and 2021, the fair value of the convertible debt and derivative liability for the March 2019 Notes is $10.8 million and $12.3 million, respectively.

The March 2019 Notes were issued and sold for cash at a purchase price equal to 100% of their principal amount, in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended (the

"Securities Act"), due to the March 2019 Notes being issued to one financially sophisticated investor. The March 2019 Notes bear interest at a rate of 6.0% per annum payable semiannually in arrears on March 15 and September 15 of each year, beginning September 15, 2019. The March 2019 Notes will mature on March 15, 2025, unless earlier converted, redeemed or repurchased. The March 2019 Notes constitute general, senior unsecured obligations of the Company.

The holder of the March 2019 Notes may convert their March 2019 Notes at their option at any time prior to the close of business on the business day immediately preceding March 15, 2025 into shares of the Company's common stock. The initial conversion rate is 73.9096 shares of common stock per $1,000 principal amount of March 2019 Notes, which is equivalent to an initial conversion price of approximately $13.53 and is subject to adjustment in certain events described in the March 2019 Note Purchase Agreement. The Holder upon conversion may also be entitled to receive, under certain circumstances, an interest make-whole payment payable in shares of common stock. In addition, following certain corporate events that occur prior to the maturity date, the Company will, in certain circumstances, increase the conversion rate if the holder elects to convert its March 2019 Notes in connection with such a corporate event. Subject to adjustment in the conversion rate, the number of shares that the Company may deliver in connection with a conversion of the March 2019 Notes, including those delivered in connection with an interest make-whole payment, will not exceed a cap of 81 shares of common stock per $1,000 principal amount of the March 2019 Notes.

On or after March 15, 2022, the Company has the right, at its election, to redeem all or any portion of the March 2019 Notes not previously converted if the last reported sale price per share of common stock exceeds 130% of the conversion price on each of at least 20 trading days (whether or not consecutive) during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related redemption notice. The redemption price will be 100% of the principal amount of the March 2019 Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. If a "fundamental change" (as defined in the March 2019 Note Purchase Agreement) occurs, then, subject to certain exceptions, the Company must offer to repurchase the March 2019 Notes for cash at a repurchase price of 100% of the principal amount of the March 2019 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the repurchase date.

Other Liabilities

In February 2021, the Company partnered with Amplity for the commercial launch of BREXAFEMME for the treatment of VVC. Under the terms of the agreement with Amplity, the Company was to utilize Amplity's commercial execution and resources for sales force, remote engagement, training, market access and select operations services. In October 2022, the Company announced that it was actively pursuing a U.S. commercialization partner to out-license BREXAFEMME in order to refocus the Company's resources on the further clinical development of ibrexafungerp for severe, hospital-based indications. As a result, the Company wound down its promotional activities associated with BREXAFEMME, while keeping BREXAFEMME on the market and available to patients. On November 30, 2022, the Company terminated the agreement with Amplity.

Under the terms of the original agreement, Amplity deferred a portion of its direct service fees in the first two years (2021 and 2022) that accrued interest at an annual rate of 12.75% ("Deferred Fees"). As of December 31, 2022, Deferred Fees of $5.8 million, which includes a portion of the $1.5 million termination fee that was unpaid as of December 31, 2022, are recognized as short term other liabilities in the consolidated balance sheets. The $5.8 million of Deferred Fees as of December 31, 2022 was fully paid as of February 2023. Additionally, as a result of the reduction in internal workforce in the Company's commercial function in 2022, the Company recognized $1.3 million in severance costs during the year ended December 31, 2022.

9. Commitments and Contingencies

Leases

On March 1, 2018, the Company entered into a long-term lease agreement for approximately 19,275 square feet of office space in Jersey City, New Jersey, that the Company identified as an operating lease under ASC 842 (the "Lease"). The lease term is eleven years from August 1, 2018, the commencement date, with total lease payments of $7.3 million over the lease term. The Company has the option to renew for two consecutive five-year periods from the end of the first term and the Company is not reasonably certain that the option to renew the Lease will be exercised. Under the Lease, the Company furnished a security deposit in the form of a standby letter of credit in the amount of $0.3 million, which will be reduced by fifty-five thousand dollars every two years for ten years after the commencement of the lease. The security deposit is classified as restricted cash in the accompanying consolidated balance sheets.

The consideration in the Lease allocated to the single lease component includes the fixed payments for the right to use the office space as well as common area maintenance. The Lease also contains costs associated with certain expense escalation, property taxes, insurance, parking, and utilities which are all considered variable payments and are excluded from the operating

lease liability. The incremental borrowing rate utilized approximated the prevailing market interest rate the Company would incur to borrow a similar amount equal to the total Lease payments on a collateralized basis over the term of the Lease. The following table summarizes certain quantitative information associated with the amounts recognized in the accompanying consolidated financial statements for the Lease (dollars in thousands):

	Years Ended December 31,	
	2022	2021
Operating lease cost	$ 664	$ 664
Variable lease cost	49	38
Total operating lease expense	$ 713	$ 702
Cash paid for amounts included in the measurement of operating lease liability	$ 527	$ 517

	December 31, 2022	December 31, 2021
Remaining Lease term (years)	6.59	7.59
Discount rate	15%	15%

Future minimum lease payments for all operating leases as of December 31, 2022 are as follows (in thousands):

	December 31, 2022
2023	$ 715
2024	730
2025	744
2026	759
2027	774
Thereafter	1,256
Total	$ 4,978

The presentation of the operating lease liability as of December 31, 2022 is as follows (in thousands):

	December 31, 2022
Present value of future minimum lease payments	$ 3,203
Operating lease liability, current portion	$ 282
Operating lease liability, long-term portion	2,921
Total operating lease liability	$ 3,203
Difference between future minimum lease payments and discounted cash flows	$ 1,775

License Arrangements with Potential Future Expenditures

As of December 31, 2022, the Company had a license arrangement with Merck Sharp & Dohme Corp., or Merck, as amended, that involves potential future expenditures. Under the license arrangement, executed in May 2013, the Company exclusively licensed from Merck its rights to ibrexafungerp in the field of human health. In January 2014, Merck assigned the patents related to ibrexafungerp that it had exclusively licensed to the Company. Ibrexafungerp is the Company's lead product candidate. Pursuant to the terms of the license agreement, Merck was originally eligible to receive milestone payments from the Company that could total $19.0 million upon occurrence of specific events, including initiation of a Phase 2 clinical study, new drug application, and marketing approvals in each of the U.S., major European markets, and Japan. In addition, Merck is eligible to receive tiered royalties from the Company based on a percentage of worldwide net sales of ibrexafungerp. The aggregate royalties are mid- to high-single digits.

In December 2014, the Company and Merck entered into an amendment to the license agreement that deferred the remittance of a milestone payment due to Merck, such that no amount would be due upon initiation of the first Phase 2 clinical trial of a product containing the ibrexafungerp compound (the “Deferred Milestone”). The amendment also increased, in an amount equal to the Deferred Milestone, the milestone payment that would be due upon initiation of the first Phase 3 clinical trial of a product containing the ibrexafungerp compound. In December 2016 and January 2018, the Company entered into second and third amendments to the license agreement with Merck which clarified what would constitute the initiation of a Phase 3 clinical trial for the purpose of milestone payment. In January 2019, a milestone payment became due to Merck as a

result of the initiation of the VANISH Phase 3 VVC program and was paid in March 2019. On December 2, 2020, the Company entered into a fourth amendment to the license agreement with Merck. The amendment eliminates two cash milestone payments that the Company would have paid to Merck upon the first filing of a NDA, triggered by the FDA acceptance for filing of its NDA for ibrexafungerp for the treatment of VVC, and first marketing approval in the U.S., in June 2021 for the Company's NDA for ibrexafungerp for the treatment of VVC. Such cash milestone payments would have been creditable against future royalties owed to Merck on net sales of ibrexafungerp. With the amendment, these milestones will not be paid in cash and, accordingly, credits will not accrue. Pursuant to the amendment, the Company will also forfeit the credits against future royalties that it had accrued from a prior milestone payment already paid to Merck. All other key terms of the license agreement are unchanged.

Clinical Development Arrangements

The Company has entered into, and expects to continue to enter into, contracts in the normal course of business with various third parties who support its clinical trials, preclinical research studies, and other services related to its development activities. The scope of the services under these agreements can generally be modified at any time, and the agreement can be terminated by either party after a period of notice and receipt of written notice.

10. Stockholders' Equity

Authorized, Issued, and Outstanding Common Shares

The Company's authorized common stock has a par value of $0.001 per share and consists of 150,000,000 shares as of December 31, 2022 and 100,000,000 shares as of December 31, 2021; 32,682,342 and 28,705,334 shares were issued and outstanding at December 31, 2022 and 2021, respectively. In September 2022, the Company amended its Amended and Restated Certificate of Incorporation to increase the total number of authorized shares of common stock from 100,000,000 to 150,000,000.

Shares Reserved for Future Issuance

The Company had reserved shares of common stock for future issuance as follows:

	December 31,	
	2022	2021
Outstanding stock options	1,740,308	1,542,126
Outstanding restricted stock units	633,270	133,834
Warrants to purchase common stock associated with March 2018 public offering - Series 2	798,810	798,810
Warrants to purchase common stock associated with December 2020 public offering - Series 2	6,800,000	6,800,000
Prefunded warrants to purchase common stock associated with December 2020 public offering	3,200,000	3,200,000
Warrants to purchase common stock associated with April 2022 Public Offering	15,000,000	—
Prefunded warrants to purchase common stock associated with April 2022 Public Offering	11,666,667	—
Warrants to purchase common stock associated with Loan Agreement	198,811	170,410
Warrants to purchase common stock associated with Danforth	50,000	50,000
For possible future issuance for the conversion of the March 2019 Notes	1,138,200	1,138,200
For possible future issuance under 2014 Plan (Note 13)	712,020	295,220
For possible future issuance under employee stock purchase plan	—	3,893
For possible future issuance under 2015 Plan (Note 13)	550,964	235,000
Total common shares reserved for future issuance	42,489,050	14,367,493

Liquidation Rights

In the event of any liquidation or dissolution of the Company, the holders of the common stock are entitled to the remaining assets of the Company legally available for distribution.

Dividends and Voting Rights

The holders of the common stock are entitled to receive dividends if and when declared by the Company.

Preferred Stock

On May 7, 2014, the Company amended and restated its articles of incorporation relating to its approved capital structure. The Company's board of directors has authorized the Company, subject to limitations prescribed by Delaware law, to issue up

to 5,000,000 shares of preferred stock with a par value of $0.001 per share in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations or restrictions. The Company's board of directors can also increase or decrease the number of shares of any series of preferred stock, but not below the number of shares of that series then outstanding, without any further vote or action by the stockholders. The Company's board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. There were no shares of preferred stock issued and outstanding as of December 31, 2022 and 2021.

Common Stock Purchase Agreement and Sales Agreements

On April 10, 2020, the Company entered into the Common Stock Purchase Agreement with Aspire Capital (the "Common Stock Purchase Agreement") pursuant to which the Company had the right to sell to Aspire Capital from time to time in its sole discretion up to $20.0 million in shares of the Company's common stock, subject to certain limitations and conditions set forth in the Common Stock Purchase Agreement. The Common Stock Purchase Agreement expired in October 2022. During the years ended December 31, 2022 and 2021, the Company sold 425,000 and 400,000 shares of its common stock under the Common Stock Purchase Agreement for gross proceeds of $1.6 million and $2.6 million, respectively.

During the years ended December 31, 2022, and 2021, the Company sold 137,610 and 494,406 shares of its common stock and received net proceeds of $0.7 million and $3.1 million, respectively, under the Controlled Equity OfferingSM Sales Agreements with Cantor Fitzgerald & Co. and Ladenburg Thalmann & Co. Inc. (the "Sales Agreements").

April 2022 Public Offering

On April 22, 2022, the Company entered into an Equity Underwriting Agreement (the "Underwriting Agreement") with Guggenheim Securities, LLC, as representative of the several underwriters (the "Underwriters"), relating to the offering, issuance and sale (the "April 2022 Public Offering") of (a) 3,333,333 shares of the Company's common stock, par value $0.001 per share, (b) prefunded warrants, in lieu of common stock, to purchase 11,666,667 shares of the Company's common stock, par value $0.001 per share, and (c) warrants, which will accompany the common stock or prefunded warrants, to purchase up to an aggregate of 15,000,000 shares of the Company's common stock. The prefunded warrants entitle the holders to purchase up to 11,666,667 shares of common stock and have an unlimited term and an exercise price of $0.001 per share. The warrants entitle the holders to purchase up to an aggregate of 15,000,000 shares of common stock and have a seven-year term and an exercise price of $3.45 per share. The warrants that accompany the prefunded warrants have an additional provision entitling the holder thereof to purchase a prefunded warrant rather than a share of common stock at the warrant exercise price less the exercise price of the prefunded warrant purchased. Each warrant is exercisable immediately upon issuance, subject to certain limitations on beneficial ownership. The price to the public in the April 2022 Public Offering was $3.00 per share of common stock and accompanying warrants, or in the case of prefunded warrants, $2.999 per prefunded warrant and accompanying warrants, which resulted in $41.8 million of net proceeds to the Company after deducting the underwriting discount and offering expenses.

The prefunded warrants are classified as equity in accordance with ASC 815, *Derivatives and Hedging*, given the prefunded warrants are indexed to the Company's own shares of common stock and meet the requirements to be classified in equity. The prefunded warrants were recorded at their relative fair value at issuance in the stockholders' equity section of the balance sheet and the prefunded warrants are considered outstanding shares in the basic earnings per share calculation for the year ended December 31, 2022 given their nominal exercise price.

December 2020 Public Offering Warrants

On December 17, 2020, the Company completed a public offering (the "December 2020 Public Offering") of its common stock and warrants pursuant to the Company's effective shelf registration. The Company sold an aggregate of (a) 8,340,000 shares of the Company's common stock, par value $0.001 per share, (b) prefunded warrants, in lieu of common stock, to purchase 5,260,000 shares of the Company's common stock, par value $0.001 per share, and (c) two series of warrants, which will accompany the common stock or prefunded warrants, to purchase up to an aggregate of 13,600,000 shares of the Company's common stock. The prefunded warrants entitle the holders to purchase up to 5,260,000 shares of common stock and have an unlimited term and an exercise price of $0.001 per share. During the year ended December 31, 2021, 2,060,000 of the prefunded warrants were exercised for proceeds of $2,000. Each of the two series of warrants entitle the holders to purchase up to an aggregate of 6,800,000 shares of common stock.

The prefunded warrants are classified as equity in accordance with ASC 815, *Derivatives and Hedging*, given the prefunded warrants are indexed to the Company's own shares of common stock and meet the requirements to be classified in equity. The prefunded warrants were recorded at their relative fair value at issuance in the stockholders' equity section of the balance sheet and the prefunded warrants are considered outstanding shares in the basic earnings per share calculation for the years ended December 31, 2022 and 2021 given their nominal exercise price.

The Series 1 warrants had a one-year term and an exercise price of $7.33 per share, and the Series 2 warrants have a three-and-a-half-year term and an exercise price of $8.25 per share. There is not expected to be any trading market for the prefunded warrants, the Series 1 warrants, or the Series 2 warrants issued in the offering. Each warrant is exercisable immediately upon issuance, subject to certain limitations on beneficial ownership. The Series 1 and Series 2 warrants that accompany the prefunded warrants have an additional provision, if certain beneficial ownership limitations are met, entitling the holder thereof to purchase a prefunded warrant rather than a share of common stock at the warrant exercise price less the exercise price of the prefunded warrant purchased. The price to the public in the offering was $6.25 per share of common stock and accompanying warrants, or in the case of prefunded warrants, $6.249 per prefunded warrant and accompanying warrants. In June 2021, 360,134 of the December 2020 Series 1 public offering warrants were exercised for proceeds of $2.6 million.

On December 21, 2021, the Board of Directors approved a modified exercise price of $6.25 per common share for up to 6,100,000 of the Series 1 warrants. 5,980,800 of the Series 1 warrants were repriced at $6.25 per common share and 3,370,800 were exercised for gross proceeds of $21.1 million which was received by the Company in December 2021. Of the 3,370,800 warrants exercised by the warrant holders, 2,390,000 warrants were held by 5% beneficial owners of the Company for gross proceeds of $14.9 million. The 3,370,800 Series 1 warrants were ultimately fair valued with the resulting change in fair value recognized in earnings. The resulting fair value of the 3,370,800 was $1.9 million and the Company recognized the change in fair value in earnings of $1.4 million. On the settlement date, the contractual liability value of $1.9 million for the 3,370,800 Series 1 warrants was derecognized and included in additional paid in capital as part of the settlement. The remaining Series 1 warrants expired unexercised on December 21, 2021 and the remaining liability balance was derecognized.

On November 24, 2021, an investor provided a conversion notice of 160,000 shares for gross proceeds to the Company of $1.2 million which was received in November 2021. As a result, the 160,000 Series 1 warrants were fair valued with the resulting change in fair value recognized in earnings. The resulting fair value of the 160,000 Series 1 warrants was $0.1 million and the Company recognized the change in fair value in earnings of $0.1 million. On the settlement date, the contractual liability value of $0.1 million for the 160,000 Series 1 warrants was derecognized and included in additional paid in capital as part of the settlement.

December 2019 Public Offering Warrants

On December 12, 2019, the Company completed a public offering (the "December 2019 Public Offering") of its common stock and warrants pursuant to the Company's effective Shelf Registration. The Company sold an aggregate of 3,888,888 shares of the Company's common stock and warrants to purchase up to an aggregate of 3,888,888 shares of the Company's common stock at a public offering price of $9.00 per share and accompanying warrant. Net proceeds from the December 2019 Public Offering were approximately $32.5 million, after deducting the underwriting discount and offering expenses.

The warrants to purchase shares of common stock are immediately exercisable and expire on the earlier of (i) such date that is six months after the Company publicly announces the approval from the U.S. Food and Drug Administration for ibrexafungerp for the treatment of vulvovaginal candidiasis and (ii) June 12, 2023, and have an exercise price of $11.0 per share. There is not expected to be any trading market for the warrants. Each warrant is exercisable immediately upon issuance, subject to certain limitations on beneficial ownership.

On November 26, 2021, the Board of Directors approved a modified exercise price of $6.50 per common share for 1,111,111 of the warrants issued to a 5% beneficial owner and investor of the Company and no other terms of the original warrant were modified. On November 30, 2021, the investor provided a notice to exercise 1,111,111 of 2019 Warrants for proceeds of $7.2 million which was received by the Company on December 1, 2021. On the settlement date, the contractual liability value of $0.2 million for the 1,111,111 warrants was derecognized and included in additional paid in capital as part of the settlement. Additionally, on December 2, 2021, the Board of Directors also approved a reduced exercise price of $6.50 per common share for 361,111, 827,777, 194,444, and 111,111 of the warrants issued to certain investors. On December 2, 2021, one investor provided a notice to exercise 111,111 of the warrants for proceeds of $0.7 million which was received by the Company in December 2021. As a result, the 111,111 warrants were fair valued on December 2, 2021 with the resulting change in fair value recognized in earnings. The resulting fair value of the 111,111 warrants was $19,000 and the Company recognized the change in fair value in earnings of $18,000. On the settlement date, the contractual liability value of $19,000 for the 111,111 warrants was derecognized and included in additional paid in capital as part of the settlement. The remaining 2019 Warrants expired unexercised (including the 2019 Warrants that had a revised exercise price that went unexercised) on December 2, 2021 and the remaining liability balance was derecognized.

March 2018 Public Offering Warrants

On March 8, 2018, the Company completed a public offering (the "March 2018 Public Offering") of its common stock and warrants pursuant to the Company's effective shelf registration. The Company sold an aggregate of 1,775,150 shares of the Company's common stock and warrants to purchase up to 2,130,180 shares of the Company's common stock at a public offering price of $16.90 per share.

Each purchaser received a warrant to purchase 0.75 of a share of common stock (the "March 2018 Series 1 warrants") and 0.45 of a share of common stock (the "March 2018 Series 2 warrants") for each share purchased in the March 2018 Public Offering. The March 2018 Series 1 warrants to purchase in the aggregate up to 1,331,370 shares of common stock had a 53-week term and an exercise price of $18.5 per share, and the March 2018 Series 2 warrants to purchase in the aggregate up to 798,810 shares of common stock have a five-year term and an exercise price of $20.0 per share. There is not expected to be any market for the warrants and each warrant is exercisable immediately upon issuance, subject to certain limitations on beneficial ownership.

Public Offering Warrant Liabilities

The March 2018, December 2019, and December 2020 warrants contain a provision where the warrant holder has the option to receive cash, equal to the Black-Scholes fair value of the remaining unexercised portion of the warrant, as cash settlement in the event that there is a fundamental transaction (contractually defined to include various merger, acquisition or stock transfer activities). Due to this provision, ASC 480, *Distinguishing Liabilities from Equity*, requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Black-Scholes valuation model, and the changes in the fair value are recorded in the accompanying consolidated statements of operations. The outstanding warrants associated with the April 2022 Public Offering meet the definition of a derivative pursuant to ASC 815, *Derivatives and Hedging*, and do not meet the derivative scope exception given the warrants do not qualify under the indexation guidance. As a result, the April 2022 Public Offering warrants were initially recognized as liabilities and measured at fair value using the Black-Scholes valuation model. During the years ended December 31, 2022 and 2021, the Company recorded gains of $22.3 million and $30.4 million, respectively, due to the change in fair value of the warrant liabilities. Issuance costs of $1.7 million initially allocated to the April 2022 Public Offering warrant liabilities were written off upon settlement and were recognized in the gain on the fair value adjustment for the warrant liabilities for the year ended December 31, 2022. As of December 31, 2022, the fair value of the warrant liabilities was $18.6 million.

Warrant Associated with Danforth Advisors

Pursuant to a consulting agreement with Danforth Advisors ("Danforth") entered into in November 2021, the Company issued to Danforth a warrant to purchase 50,000 shares of the Company's common stock at an exercise price of $5.50 per share. The warrant will expire five years from the date of the grant and will vest ratably over 24 months from the date of grant. The warrant was classified as equity and was initially fair valued using the Black-Scholes model on the grant date. In accordance with ASC 718, the Company recognized consulting expense for the non-employee share-based payment over the period the Company received Danforth's services.

11. Revenue

Product Revenue, Net

Net product revenue was $5.0 million and $1.1 million for the years ended December 31, 2022 and 2021, respectively. Products are sold primarily to wholesalers and specialty pharmacies. Revenue is reduced from wholesaler list price at the time of recognition for expected chargebacks, rebates, discounts, incentives, and returns, which are referred to as gross to net ("GTN") adjustments. These reductions are currently attributed to various commercial arrangements. Chargebacks and discounts are recognized as a reduction in accounts receivable or as accrued expenses based on their nature and settled through the issuance of credits to the customer or through cash payments to the customer, respectively. All other returns, rebates, and incentives are reflected as accrued expenses and settled through cash payments to the customer. Three wholesalers comprised 45%, 28%, and 21% of the Company's gross revenue for the year ended December 31, 2022, and 47%, 25%, and 23% of the Company's gross revenue for the year ended December 31, 2021.

The following table summarizes activity in each of the Company's product revenue provision and allowance categories as of December 31, 2022 and 2021 (in thousands):

	Discounts and Chargebacks (1)	Product Returns (2)	Rebates and Incentives (3)	Total
Balance as of December 31, 2020	$ —	$ —	$ —	$ —
Provision related to current period revenue	720	21	2,365	3,106
Changes in estimate related to prior period revenue	—	—	—	—
Credit/payments	(471)	—	(1,255)	(1,726)
Balance as of December 31, 2021	$ 249	$ 21	$ 1,110	$ 1,380
Provision related to current period revenue	1,493	52	3,916	5,461
Changes in estimate related to prior period revenue	—	—	—	—
Credit/payments	(1,487)	—	(3,813)	(5,300)
Balance as of December 31, 2022	$ 255	$ 73	$ 1,213	$ 1,541

(1) Discounts and chargebacks include fees for wholesaler fees, prompt pay and other discounts, and chargebacks. Discounts and chargebacks are deducted from gross revenue at the time revenues are recognized and are included as a reduction in accounts receivable or as an accrued expense based on their nature on the Company's consolidated balance sheet.
(2) Provisions for product returns are deducted from gross revenues at the time revenues are recognized and are included in accrued expenses on the Company's consolidated balance sheet.
(3) Rebates and incentives include rebates and co-pay program incentives. Provisions for rebates and incentives are deducted from gross revenues at the time revenues are recognized and are included in accrued expenses on the Company's consolidated balance sheets.

License Agreement Revenue

In February 2021, the Company entered into an Exclusive License and Collaboration Agreement (the "Agreement") with Hansoh (Shanghai) Health Technology Co., Ltd., and Jiangsu Hansoh Pharmaceutical Group Company Limited (collectively, "Hansoh"), pursuant to which the Company granted to Hansoh an exclusive license to research, develop and commercialize ibrexafungerp in the Greater China region, including mainland China, Hong Kong, Macau, and Taiwan (the "Territory"). The Company also granted to Hansoh a non-exclusive license to manufacture ibrexafungerp solely for development and commercialization in the Territory. Under the terms of the Agreement, Hansoh shall be responsible for the development, regulatory approval and commercialization of ibrexafungerp in the Territory.

Pursuant to the terms of the Agreement, the Company received as consideration for the licenses a nonrefundable upfront cash payment of $10.0 million and is entitled to an additional payment that was payable upon the transfer of certain data related to the manufacturing license. In addition, the Company will also be eligible to receive up to $110.0 million in potential development and commercial milestones. In addition, during the term of the licensing agreement, the Company is entitled to low double-digit royalties on net product sales. The obligation to pay royalties with respect to sales in a specified region will continue until the later of the date of expiration of all intellectual property and regulatory exclusivity for the product in the region and ten years from the first commercial sale, unless earlier terminated by Hansoh with advanced notice for convenience or under other specified circumstances. The Company is also eligible to receive a milestone related to the successful completion of a manufacturing batch by Hansoh.

The Company evaluated the Agreement and concluded that it was subject to ASC 606 as the Company viewed the Agreement as a contract with a customer as the activities were central to its business operations. As such, the Company assessed the terms of the Agreement and identified one performance obligation for the licenses to research, develop, manufacture and commercialize ibrexafungerp in the Territory, including the underlying know-how related to such licenses. The Company also evaluated options for additional goods and services included in the Agreement related to (1) optional technical assistance related to development, regulatory or manufacturing activities and (2) a supply agreement for ibrexafungerp. Such options for additional goods or services were not considered to contain material rights as pricing approximated standalone selling prices and therefore the Company concluded that such options did not represent performance obligations and will be accounted for as separate transactions if and when they occur in the future.

The Company determined that the transaction price of $12.1 million included the fixed upfront cash payment of $10.0 million, an additional amount that was payable upon the transfer of certain data related to the manufacturing license, and $1.1 million related to withholding tax obligations that Hansoh remitted on behalf of the Company. The remaining amounts related to the successful completion of a manufacturing batch by Hansoh and potential development milestones represent variable consideration and were constrained as it was concluded that it was not probable that a significant reversal in cumulative revenue recognized will not occur and therefore not included in the transaction price as of December 31, 2022 and 2021. Potential commercial milestones and royalties on net product sales will be recognized in the same period that the underlying net product sales occur as they were determined to relate to the license. The transaction price was recorded in revenue during the year ended December 31, 2021 at a point in time upon control of the license transferring to Hansoh. The Company will reevaluate the transaction price at the end of each reporting period as uncertain events or resolved, or as other changes in circumstances occur.

Additionally, pursuant to the Agreement, both the Company and Hansoh agreed to make reasonable efforts to account for applicable taxes, fees, duties, levies, or similar amounts imposed on net income, franchise taxes and profits arising directly or indirectly from the activities of the Agreement. To the extent Hansoh is required by applicable laws to withhold or deduct any tax on any payment to the Company, Hansoh agreed to make certain increases on payments to the Company to ensure that the Company receives a sum equal to what the Company would have received had there been no deduction or withholding. As a result, the Company has recorded revenue and tax withholding expense primarily associated with the up-front payment received by the Company on a gross basis. For the year ended December 31, 2021, the Company recognized $1.1 million in revenue

and $1.1 million in income tax expense to account for the tax withholding expense primarily on the $10.0 million up-front that the Company is responsible to remit under applicable tax law.

In July 2016, the Company entered into an asset purchase agreement with UK-based Cypralis Limited (or "Cypralis"), a life sciences company, for the sale of its cyclophilin inhibitor assets. Cypralis also acquired all patents, patent applications and know-how related to the acquired portfolio. In connection with the asset purchase agreement, the Company is eligible to receive milestone payments upon the successful progression of Cypralis clinical candidates into later stage clinical studies and royalties payable upon product commercialization. The Company retains the right to repurchase the portfolio assets from Cypralis if abandoned or deprioritized. For the years ended December 31, 2022 and 2021, there was no revenue recognized associated with this agreement given the variable consideration associated with the sale of intellectual property to Cypralis was fully constrained as of December 31, 2022. Additionally, in October 2014 the Company entered into a license agreement with Waterstone Pharmaceutical HK Limited (or “Waterstone”) and granted Waterstone an exclusive, worldwide license to develop and commercialize certain non-strategic compounds. The Company is entitled to receive potential milestones and royalties from Waterstone; however, there was no revenue recognized by the Company in 2022 and 2021 associated with this agreement given the variable consideration was fully constrained as of December 31, 2022 and 2021.

12. Income Taxes

The Company’s consolidated financial statements include a total tax benefit of $4.7 million and $3.1 million on loss before taxes of $67.5 million and $36.0 million for the years ended December 31, 2022 and 2021, respectively. The income tax benefit consisted of the following (dollars in thousands):

	Years Ended December 31,	
	2022	2021
Current (benefit) expense		
U.S.	$ (4,700)	$ (4,188)
Non-U.S	—	1,100
Total current (benefit)	$ (4,700)	$ (3,088)

Reconciliations of the differences between the benefit for income taxes and income taxes at the statutory U.S. federal income tax rate is as follows (dollars in thousands):

	2022		2021	
	Amount	Percent of Pretax Income	Amount	Percent of Pretax Income
Income taxes from continuing operations at statutory rate	$ (13,176)	21.0%	$ (7,781)	21.0%
State income taxes	(319)	0.5%	(1,144)	3.1%
State effect of permanent items	(114)	0.2%	(906)	2.4%
Foreign withholding taxes	—	—	1,100	(3.0)%
Stock-based compensation	123	(0.2)%	114	(0.3)%
Deferred rate change	379	(0.6)%	339	(0.9)%
Warrants issuance	(4,960)	7.9%	(6,622)	17.9%
Other	713	(1.2)%	(489)	1.3%
NOL sale	237	(0.4)%	214	(0.6)%
R&D credit adjustment	—	—	—	—
Increase in valuation allowance	12,417	(19.8)%	12,087	(32.6)%
Total income tax (benefit)	$ (4,700)	7.4%	$ (3,088)	8.3%

The components of deferred tax assets and liabilities as of December 31, 2022 and 2021 are as follows (in thousands):

	December 31,	
	2022	2021
Noncurrent deferred tax assets (liabilities)		
Accrued expenses	$ 578	$ 1,264
Stock-based compensation	2,675	2,554
Lease liability	689	789
Other	4,398	(757)
Net operating loss carryforwards	88,363	80,453
Research and development credits	6,839	6,839
Total deferred tax assets	103,542	91,142
Valuation allowances	(103,542)	(91,142)
Net deferred tax assets	$ —	$ —

As of December 31, 2022 and 2021, the Company had available federal net operating loss ("NOL") carryforwards of approximately $405.0 million and $348.4 million, respectively, and state and net operating loss carryforwards of approximately $116.8 million and $186.3 million, respectively. Approximately $169.6 million of the federal NOLs can be carried forward to future tax years and expire at various times through 2037. The federal NOLs generated in December 31, 2022 and 2021 of approximately $56.6 million and $55.7 million, respectively, are carried forward indefinitely and do not expire. The Company's state and net operating loss carryforwards began to expire in 2019. As of December 31, 2022, the Company had available federal research and development credit carryforwards of $6.6 million which began to expire in 2022.

The New Jersey Technology Business Tax Certificate Transfer (NOL) program, administered by the New Jersey Economic Development Authority, enables approved biotechnology companies to sell their unused net operating losses ("NOLs") and research and development tax credits to unaffiliated, profitable corporate taxpayers in the State of New Jersey ("NJ") up to a maximum lifetime benefit of $20.0 million per business. As of December 31, 2022, the Company has received approximately $18.8 million under the program. In February 2022 and April 2021, the Company received cash receipts of $4.7 million and $4.1 million, respectively, from the sale of its NJ state NOLS. The Company recognized an income tax benefit of $4.7 million and $4.1 million for the years ended December 31, 2022 and 2021, respectively, in the statement of operations.

As part of the license agreement with Hansoh, the Company and Hansoh agreed to make reasonable efforts to account for applicable taxes, fees, duties, levies, or similar amounts imposed on net income, franchise taxes and profits arising directly or indirectly from the activities of the license agreement. To the extent Hansoh is required by applicable laws to withhold or deduct any tax on any payment to the Company, Hansoh agreed to make certain increases on payments to the Company to ensure that the Company receives a sum equal to what the Company would have received had there been no deduction or withholding. As a result, the Company has recorded revenue and tax withholding expense primarily associated with the up-front payment received by the Company on a gross basis. For the year ended December 31, 2021, the Company recognized $1.1 million in license agreement revenue and $1.1 million in income tax expense to account for the tax withholding expense primarily on the $10.0 million up-front that the Company is responsible to remit under applicable tax law.

On December 22, 2017, the "Tax Cuts and Jobs Act" was signed into law. The tax reform has the following effects on the Company: (1) permanently reduces the maximum corporate income tax rate from 35% to 21% effective for tax years beginning after December 31, 2017, (2) allows temporary 100% expensing for certain business assets and property placed in service after September 27, 2018 and before January 1, 2023, (3) disallows NOL carrybacks but allows for the indefinite carryforward of those NOLs which applies to losses arising in tax years beginning after December 31, 2018 and, (4) limits NOL deductions for each year equal to the lesser of the available carryover or 80% of a taxpayer's pre-NOL deduction taxable income. This applies to losses arising in tax years ending on or after December 31, 2017. As of December 31, 2022 and 2021, the Company has concluded that it is more likely than not that the Company will not realize the benefit of its deferred tax assets due to its history of losses. Accordingly, the net deferred tax assets have been fully reserved.

In accordance with Section 382 of the Internal Revenue Code of 1986, as amended, a change in equity ownership of greater than 50% within a three-year period results in an annual limitation on the Company's ability to utilize its NOL carryforwards created during the tax periods prior to the change in ownership. The Company has determined that ownership changes have occurred and as a result, a portion of the Company's NOL carryforwards are limited. Because the Company has incurred cumulative net operating losses since inception, all tax years remain open to examination by U.S. federal and state income tax authorities.

The Company applies ASC 740-10-25-5, *Income Taxes*, formerly FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, as amended, on January 1, 2009. The difference between the tax benefit recognized in the financial statements and the tax benefit claimed in the tax return is referred to as an unrecognized tax benefit.

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits as of December 31, 2022 and 2021 (in thousands):

	December 31,	
	2022	2021
Unrecognized tax benefit—January 1	$ 436	$ 436
Additions for tax positions of current period	—	—
Additions for tax positions of prior periods	—	—
Deferred rate change	—	—
Unrecognized tax benefit—December 31	$ 436	$ 436

None of the unrecognized tax benefits would, if recognized, affect the effective tax rate because the Company has recorded a valuation allowance to fully offset federal and state deferred tax assets. The Company has no tax positions for which it is reasonably possible that the total amount of unrecognized tax benefits will significantly increase or decrease within the coming year. The Company has $0 provided for interest and penalties associated with uncertain tax positions.

13. Stock-based Compensation

2009 Stock Option Plan

The Company had a share-based compensation plan (the "2009 Stock Option Plan") under which the Company granted options to purchase shares of common stock to employees, directors, and consultants as either incentive stock options or nonqualified stock options. Incentive stock options could be granted with exercise prices not less than 100% to 110% of the fair market value of the common stock. Options granted under the plan generally vest over three to four years and expire in 10 years from the date of grant.

2014 Equity Incentive Plan

In February 2014, the Company's board of directors adopted the 2014 Equity Incentive Plan ("2014 Plan"), which was subsequently ratified by its stockholders and became effective on May 2, 2014 (the "Effective Date"). The 2014 Plan, as amended on June 18, 2014 and February 25, 2015, is the successor to and continuation of the 2009 Stock Option Plan. As of the Effective Date, no additional awards will be granted under the 2009 Stock Option Plan, but all stock awards granted under the 2009 Stock Option Plan prior to the Effective Date will remain subject to the terms of the 2009 Stock Option Plan. All awards granted on and after the Effective Date will be subject to the terms of the 2014 Plan. The 2014 Plan provides for the grant of the following awards: (i) incentive stock options, (ii) nonstatutory stock options, (iii) stock appreciation rights, (iv) restricted stock awards, (v) restricted stock unit awards, and (vi) other stock awards. Employees, directors, and consultants are eligible to receive awards. Options granted under the plan generally vest over three to four years and expire in 10 years from the date of grant.

Under the 2014 Plan, after giving effect to the increases to the share reserve approved by the Company's stockholders in September 2014, and June 2015, but excluding the automatic increases discussed below, the aggregate number of shares of common stock that could be issued from and after the Effective Date (the "share reserve") could not exceed the sum of (i) 112,273 new shares, (ii) the shares that represented the 2009 Stock Option Plan's available reserve on the Effective Date, and (iii) any returning shares from the 2009 Stock Option Plan. Under the 2014 Plan, the share reserve will automatically increase on January 1st of each year, for a period of not more than 10 years, commencing on January 1, 2015, and ending on January 1, 2024, in an amount equal to 4.0% of the total number of shares of capital stock outstanding on December 31st of the preceding calendar year. The board of directors may act prior to January 1st of a given year to provide that there will be no increase in the share reserve or that the increase will be a lesser number of shares than would otherwise occur.

Pursuant to the terms of the 2014 Plan, on January 1, 2022 and 2021, the Company automatically added 1,148,213 and 786,547 shares to the total number shares of common stock available for future issuance under the 2014 Plan, respectively. As of December 31, 2022, there were 712,020 shares of common stock available for future issuance under the 2014 Plan.

2015 Inducement Plan

On March 26, 2015, the Company's board of directors adopted the 2015 Inducement Plan ("2015 Plan"). The 2015 Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other forms of equity compensation (collectively, stock awards), all of which may be granted to persons not previously employees or directors of the Company, or following a bona fide period of non-employment, as an inducement material to the individuals' entering into employment with the Company within the meaning of NASDAQ Listing Rule 5635I(4). The 2015 Plan had an initial share reserve covering 45,000 shares of common stock. On June 9, 2019, April 30, 2021, and October 18, 2022, the Company's board of directors amended the 2015 Plan, and the initial share reserve for the 2015 Plan was increased from 45,000 to 90,000, from 90,000 to 500,000, and from 500,000 to 900,000 shares of common stock, respectively. During the years ended December 31, 2022 and 2021, there were 279,000 and 187,800 granted options of

the Company's common stock under the 2015 Plan, respectively. As of December 31, 2022 and 2021, there were 550,964 and 235,000 shares of common stock available for future issuance under the 2015 Plan, respectively.

Option Valuation Method

The fair value of a stock option is estimated using an option-pricing model that takes into account as of the grant date the exercise price and expected life of the option, the current price of the underlying stock and its expected volatility, expected dividends on the stock, and the risk-free interest rate for the expected term of the option. The Company has used the simplified method in calculating the expected term of all option grants based on the vesting period. Compensation costs related to share-based payment transactions are recognized in the financial statements upon satisfaction of the requisite service or vesting requirements and forfeitures are recorded as incurred.

The Company has elected to use the Black-Scholes option-pricing model. The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable rather than for use in estimating the fair value of stock options subject to vesting and transferability restrictions. Using the Black-Scholes option-pricing model, the weighted-average fair value of options granted during 2022 and 2021 was $2.47 and $4.63 per option, respectively. The aggregate fair value of options granted during 2022 and 2021 was $2.1 million and $4.0 million, respectively. The assumptions used to estimate fair value and the resulting grant date fair values are as follows:

	Employees		Non-employee	
	Years Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
Weighted average expected volatility	73.80%	62.10%	74.20%	69.56%
Weighted average risk-free interest rate	2.45%	0.64%	3.18%	0.74%
Weighted average expected term (in years)	6.04	5.15	5.63	5.79

The activity for the 2009 Plan, 2014 Plan and 2015 Plan for the years ended December 31, 2022 is summarized as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value ($000)
Outstanding — December 31, 2021	1,542,126	$ 14.89	7.45	$ 42
Granted	834,000	$ 3.76		
Forfeited/expired	(635,818)	$ 7.62		
Outstanding — December 31, 2022	1,740,308	$ 12.21	6.16	$ —
Exercisable — December 31, 2022	1,188,912	$ 15.85	4.83	$ —
Vested or expected to vest —December 31, 2022	1,740,308	$ 12.21	6.16	$ —

The intrinsic values in the table above represent the total intrinsic value (the difference between the Company's closing stock price as of December 31, 2022, and the exercise price multiplied by the number of options).

The total fair value of shares vested for both the years ended December 31, 2022 and 2021 was $1.6 million.

As of December 31, 2022, there was approximately $1.5 million of total unrecognized compensation cost related to unvested options granted under the plans. That cost is expected to be recognized over a weighted-average period of 2.5 years.

Restricted stock unit ("RSU") activity under the 2014 Plan and 2015 Plan for the years ended December 31, 2022, is summarized as follows:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Non-vested at December 31, 2021	133,834	$ 7.98
Granted	958,465	$ 5.30
Vested	(117,831)	$ 6.67
Forfeited	(341,198)	$ 5.90
Non-vested at December 31, 2022	633,270	$ 5.29

The fair value of RSUs is based on the market price of the Company's common stock on the date of grant. RSUs generally vest 25% annually over a four year period from the date of grant. Upon vesting, the RSUs are net share settled to cover the required withholding tax with the remaining shares issued to the holder. The Company recognizes compensation expense for such awards ratably over the corresponding vesting period. As of December 31, 2022, there was approximately $2.0 million of total unrecognized compensation cost related to unvested RSU share-based compensation. That cost is expected to be recognized over a weighted-average period of 1.5 years.

2014 Employee Stock Purchase Plan

In February 2014, the Company's board of directors adopted the 2014 Employee Stock Purchase Plan ("2014 ESPP"), which was subsequently ratified by the Company's stockholders and became effective on May 2, 2014. The purpose of the 2014 ESPP is to provide means by which eligible employees of the Company and of certain designated related corporations may be given an opportunity to purchase shares of the Company's common stock, and to seek and retain services of new and existing employees and to provide incentives for such persons to exert maximum efforts for the success of the Company. Common stock that may be issued under the 2014 ESPP will not exceed 4,779 shares, plus the number of shares of common stock that are automatically added on January 1st of each year for a period of ten years, commencing on January 1, 2015 and ending on January 1, 2024, in an amount equal to the lesser of (i) 0.8% of the total number of shares of outstanding common stock on December 31 of the preceding calendar year, and (ii) 2,941 shares of common stock. Similar to the 2014 Plan, the board of directors may act prior to January 1st of a given year to provide that there will be no increase in the share reserve or that the increase will be a lesser number of shares than would otherwise occur. The 2014 ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code.

During the years ended December 31, 2022 and 2021, the Company issued 6,834 and 4,943 shares of common stock under the 2014 ESPP, respectively. During the years ended December 31, 2022 and 2021, the number of shares of common stock available for issuance under the ESPP was automatically increased by 2,941 shares. As of December 31, 2022 and 2021, there were zero and 3,893 shares of common stock available for future issuance under the 2014 ESPP, respectively.

Compensation Cost

The compensation cost that has been charged against income for stock awards under the 2009 Stock Option Plan, the 2014 Plan, the 2015 Plan, and the 2014 ESPP was $3.5 million and $2.1 million for the years ended December 31, 2022 and 2021, respectively. Additionally, during the year ended December 31, 2022, the Company recognized $0.2 million in stock based compensation associated with the Danforth warrant. The total income tax benefit recognized in the consolidated statements of operations for share-based compensation arrangements was $0 for the years ended December 31, 2022 and 2021, respectively. Cash received from options exercised was zero for the years ended December 31, 2022 and 2021, respectively.

Stock-based compensation expense related to stock options and stock awards is included in the following line items in the accompanying statements of operations (in thousands):

	Years Ended December 31,	
	2022	2021
Research and development	$ 1,076	$ 631
Selling, general and administrative	2,436	1,457
Total stock-based compensation expense	$ 3,512	$ 2,088

14. Fair Value Measurements

The carrying amounts of certain financial instruments, including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their respective fair values due to the short-term nature of such instruments.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them for each reporting period, pursuant to the policy described in Note 2.

This determination requires significant judgments to be made. The following table summarizes the conclusions reached as of December 31, 2022 and 2021 for financial instruments measured at fair value on a recurring basis (in thousands):

		Fair Value Hierarchy Classification		
	Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2022				
Cash	$ 415	$ 415	—	—
Restricted cash	218	218	—	—
Money market funds	45,399	45,399	—	—
Total assets	$ 46,032	$ 46,032	—	—
Warrant liabilities	$ 18,644	—	—	$ 18,644
Derivative liability	42	—	—	42
Total liabilities	$ 18,686	—	—	$ 18,686
December 31, 2021				
Cash	$ 310	$ 310	—	—
Restricted cash	218	218	—	—
Money market funds	104,187	104,187	—	—
Total assets	$ 104,715	$ 104,715	—	—
Warrant liabilities	$ 18,062	—	—	$ 18,062
Derivative liability	1,358	—	—	1,358
Total liabilities	$ 19,420	—	—	$ 19,420

The Company measures cash equivalents at fair value on a recurring basis. The fair value of cash equivalents is determined based on "Level 1" inputs, which consist of quoted prices in active markets for identical assets.

Level 3 financial liabilities consist of the warrant liabilities for which there is no current market such that the determination of fair value requires significant judgment or estimation. Changes in fair value measurements categorized within Level 3 of the fair value hierarchy are analyzed each period based on changes in estimates or assumptions and recorded as appropriate. The Company uses the Black-Scholes option valuation model to value the Level 3 warrant liabilities at inception and on subsequent valuation dates. This model incorporates transaction details such as the Company's stock price, contractual terms, maturity, risk free rates, as well as volatility. The unobservable input for all of the Level 3 warrant liabilities includes volatility. The historical and implied volatility of the Company, using its closing common stock prices and market data, is utilized to reflect future volatility over the expected term of the warrants. At December 31, 2022, the range and weighted average of the Level 3 volatilities utilized in the Black-Scholes model to fair value the warrant liabilities were 101.8% to 113.0% and 102.1%, respectively. The Company utilizes a probability assessment to estimate the likelihood of vesting for the remaining Loan Agreement warrants and allocated the probability of occurrence percentage to the fair values calculated.

The Company uses the binomial lattice valuation model to value the Level 3 derivative liabilities at inception and on subsequent valuation dates. This model incorporates transaction details such as the Company's stock price, contractual terms, dividend yield, risk-free rate, historical volatility, credit rating, market credit spread, and estimated effective yield. The unobservable inputs associated with the Level 3 derivative liability are adjusted equity volatility, market credit spread, and estimated yield. As of December 31, 2022, these inputs were 68.5%, 1,495 basis points, and 19.3%, respectively. The senior convertible notes are initially fair valued using the binomial lattice model and with the straight debt fair value calculated using the discounted cash flow method. The discount for lack of marketability, zero and 6.7% as of December 31, 2022 and 2021, respectively, is applied to the value of the March 2019 Notes. The residual difference represents the fair value of the embedded derivative liability and the fair value of the embedded derivative liabilities are reassessed using the binomial lattice valuation model on a quarterly basis.

A reconciliation of the beginning and ending balances for liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows (in thousands):

	Warrant Liabilities
Balance – January 1, 2022	$ 18,062
April 2022 Public Offering warrant issuance	24,704
Loan Agreement warrants	(71)
Gain adjustment to fair value	(24,051)
Balance – December 31, 2022	$ 18,644

	Derivative Liabilities
Balance – January 1, 2022	$ 1,358
Gain adjustment to fair value	(1,316)
Balance – December 31, 2022	$ 42

15. Employee Benefit Plan

The Company has a 401(k) retirement plan, which covers all U.S. employees scheduled for and working more than 20 hours per week. The Company may provide a discretionary match with a maximum amount of 50% of the first 6% of eligible participant's compensation, which vests ratably over four years. Contributions under the plan were approximately $0.2 million and $0.3 million for the years ended December 31, 2022 and 2021, respectively.

16. Subsequent Events

License Agreement with GSK

On March 30, 2023, the Company entered into a license agreement (the "License Agreement") with GlaxoSmithKline Intellectual Property (No. 3) Limited ("GSK"). Pursuant to the terms of the License Agreement, the Company granted GSK an exclusive (even as to SCYNEXIS and its affiliates), royalty-bearing, sublicensable license for the development, manufacture, and commercialization of ibrexafungerp, including the approved product BREXAFEMME, for all indications, in all countries other than Greater China and certain other countries already licensed to third parties (the "GSK Territory"). If the existing licenses granted to or agreements with third parties are terminated with respect to any country, GSK will have an exclusive first right to negotiate with the Company to add those additional countries to the GSK Territory.

The Company retains rights to all other assets, with GSK receiving a right of first negotiation ("ROFN") to any other enfumafungin-derived compounds or products that the Company may control.

Under the terms of the License Agreement, the Company will receive an upfront payment of $90 million. The Company is also eligible to receive potential:

- regulatory approval milestone payments of up to $70 million;
- commercial milestone payments of up to $115 million based on first commercial sale in invasive candidiasis (U.S./EU);
- and sales milestone payments of up to $242.5 million based on annual net sales, with a total of $77.5 million to be paid upon achievement of multiple thresholds up through $200 million; a total of $65 million to be paid upon achievement of multiple thresholds between $300 million and $500 million; and $50 million to be paid at each threshold of $750 million and $1 billion.

The Company will be responsible for the execution and costs of the ongoing clinical studies of ibrexafungerp but will have the potential to receive up to $75.5 million in success-based development milestones, which are comprised of up to $65 million for the achievement of three interim milestones associated with the Company's continued performance of the ongoing MARIO Study and $10.5 million for the successful completion of the MARIO Study.

In the case of each of the above milestones, such milestone events are defined in the License Agreement.

GSK will also pay royalties based on cumulative annual sales to the Company in the mid-single digit to mid-teen range. These royalty rates are subject to reduction, including in the event of third-party licenses, entry of a generic product, or the expiration of licensed patents.

A joint development committee will be established between GSK and the Company to coordinate and review ongoing development activities of ibrexafungerp.

Unless earlier terminated, the License Agreement will expire on a product-by-product and country-by-country basis at the end of the royalty term for such product in such country.

The Company has the right to terminate the License Agreement upon an uncured material breach by, or bankruptcy of, GSK. GSK has the right to terminate the License Agreement at any time for convenience in its entirety or on a product-by-

product and country-by-country basis, upon an uncured material breach by, or bankruptcy of, the Company, or for safety reasons.

The consummation of the transactions under the License Agreement is subject to the satisfaction of customary closing conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act"); provided, that either the Company or GSK may terminate the License Agreement if expiration or termination of the applicable waiting period under the HSR Act has not occurred within nine months of the signing of the License Agreement. The parties expect the transactions contemplated by the License Agreement to close in the second quarter of 2023.

Loan Agreement Amendment

The Company, Hercules Capital, Inc. ("Hercules Capital") and Silicon Valley Bridge Bank, N.A. ("SVB") are party to a Loan and Security Agreement dated as of May 13, 2021 (the "Loan Agreement"), pursuant to which Hercules Capital, SVB and each of the other lenders from time-to-time party to the Loan and Security Agreement (collectively, the "Lenders") loaned to the Company $35 million.

In connection with the entering into of the License Agreement, the Company entered into a First Amendment and Consent to Loan and Security Agreement with the Lenders pursuant to which the Lenders consented to SCYNEXIS entering into the License Agreement and SCYNEXIS agreed to pay to the Lenders an amount equal to the sum of (i) all outstanding principal plus all accrued and unpaid interest with respect to the amounts loaned under the Loan Agreement (approximately $35.4 million), (ii) the prepayment fee payable under Loan Agreement ($262,500), (iii) the final payment payable under Loan Agreement ($1,382,500), and (iv) all other sums, if any, that shall have become due and payable with respect to loan advances under the Loan Agreement. These payments by SCYNEXIS will become due upon the earliest of (A) one business day following receipt by SCYNEXIS of the $90 million upfront payment payable to SCYNEXIS under the License Agreement, (B) June 1, 2023, or (C) the termination of the License Agreement.

2014 Plan and 2014 ESPP Share Issuance

Pursuant to the terms of the 2014 Plan (see Note 13), on January 1, 2023, the Company automatically added 1,901,960 shares to the total number shares of common stock available for future issuance under the 2014 Plan. Pursuant to the terms of the 2014 ESPP (see Note 13), on January 1, 2023, the Company automatically added 2,941 shares to the total number shares of common stock available for future issuance under the 2014 ESPP.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of December 31, 2022, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of December 31, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. A control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met. Because of these inherent limitations, management does not expect that our internal controls over financial reporting will prevent all error and all fraud. Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013 Framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2022, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 is incorporated herein by reference from our Proxy Statement, which will be filed with the SEC within 120 days after the end of our 2022 fiscal year pursuant to Regulation 14A for our 2023 Annual Meeting of Stockholders (the "Proxy Statement"), under the captions "Executive Officers of the Company," "Proposal 1 − Election of Directors," "Information Regarding the Board and Its Committees," "Nominating and Corporate Governance Committee," "Delinquent Section Reports," (if required) and "Code of Business Conduct and Ethics."

A printed copy of the Proxy Statement will be sent, without charge, to any shareholder who requests it by writing to the Chief Financial Officer of SCYNEXIS, Inc., 1 Evertrust Plaza, 13th Floor, Jersey City, NJ 07302 - 6548.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated herein by reference from the Proxy Statement under the captions "Executive Compensation" and "Director Compensation."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 is incorporated herein by reference from the Proxy Statement, under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 is incorporated herein by reference from the Proxy Statement, under the captions "Transactions with Related Persons" and "Independence of the Board."

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 is incorporated herein by reference from the Proxy Statement, under the caption "Principal Accountant Fees and Services."

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Documents filed as part of this report:

1. List of Financial Statements

The financial statements required by this item are listed in Item 8, "Consolidated Financial Statements and Supplementary Data" and incorporated by reference herein.

2. List of Financial Statement Schedules

All schedules are omitted because they are not applicable, not required or the required information is shown in the consolidated financial statements or notes thereto.

3. Exhibits

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation. (Filed with the SEC as Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on May 12, 2014, SEC File No. 001-36365, and incorporated by reference here).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of SCYNEXIS, In. (Filed with the SEC as Exhibit 3.2 to our Form 10-Q, filed with the SEC on August 7, 2019, SEC File No. 001-36365, and incorporated by reference here).
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of SCYNEXIS, Inc. (Filed with the SEC as Exhibit 3.1 to our Form 8-K, filed with the SEC on July 16, 2020, SEC File No. 001-36365, and incorporated by reference here).
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of SCYNEXIS, Inc. (Filed with the SEC as Exhibit 3.4 to our Form 10-Q, filed with SEC on November 9, 2022, SEC File No. 001-36365, and incorporated by reference here).
3.5	Amended and Restated Bylaws, as amended and as currently in effect. (Filed with the SEC as Exhibit 3.4 to our Registration Statement on Form S-1, filed with the SEC on February 27, 2014, SEC File No. 333-194192, and incorporated by reference here).
4.1	Reference is made to Exhibits 3.1 through 3.4
4.2	Description of Common Stock (Filed with SEC as Exhibit 4.2 to our Annual Report on Form 10-K, filed with the SEC on March 29, 2022, SEC File No. 001-36365, and incorporated by reference here).
4.3	Registration Rights Agreement, dated April 10, 2020, between SCYNEXIS, Inc. and Aspire Capital Fund, LLC (Filed with the SEC as Exhibit 4.1 to our Current Report on Form 8-K, filed with the SEC on April 13, 2020, SEC File No. 001-36365, and incorporated by reference here).
10.1	Form of Indemnity Agreement between the Registrant and its directors and officers. (Filed with the SEC as Exhibit 10.1 to our Amendment No. 1 to Registration Statement on Form S-1, filed with the SEC on March 19, 2014, SEC File No. 333-194192, and incorporated by reference here).
10.2*	SCYNEXIS, Inc. Stock Option Plan, as amended and restated. (Filed with the SEC as Exhibit 10.1 to our Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2020, SEC File No. 001-36365, and incorporated by reference here).
10.3*	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Stock Option Exercise under the SCYNEXIS, Inc. Stock Option Plan, as amended and restated. (Filed with the SEC as Annex B to our Proxy Statement on Schedule 14A, filed with the SEC on August 1, 2014, SEC File No. 001-36365, and incorporated by reference here).
10.4*	SCYNEXIS, Inc. 2009 Stock Option Plan, as amended and restated. (Filed with the SEC as Exhibit 10.2 to our Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2020, SEC File No. 333-194192, and incorporated by reference here).

10.5*	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Stock Option Exercise under the SCYNEXIS, Inc. 2009 Stock Option Plan, as amended and restated. (Filed with the SEC as Exhibit 10.3 to our Amendment No. 1 to Registration Statement on Form S-1, filed with the SEC on March 19, 2014, SEC File No. 333-194192, and incorporated by reference here).
10.6*	SCYNEXIS, Inc. 2014 Equity Incentive Plan, as amended and restated, (Filed with the SEC as Exhibit 10.3 to our Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2020, SEC File No. 001-36365, and incorporated by reference here).
10.7*	SCYNEXIS, Inc. 2014 Employee Stock Purchase Plan, as amended and restated. (Filed with the SEC as Exhibit 10.4 to our Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2020, SEC File No. 333-196007, and incorporated by reference here).
10.8*	Form of Stock Option Agreement and Form of Stock Option Grant Notice under the SCYNEXIS, Inc. 2014 Equity Incentive Plan (Filed with the SEC as Exhibit 99.3 to our Registration Statement on Form S-8, filed with the SEC on May 16, 2014, SEC File No. 333-196007, and incorporated by reference here).
10.9#	Development, License and Supply Agreement, dated August 1, 2013, between SCYNEXIS, Inc. and R-Pharm, CJSC. (Filed with the SEC as Exhibit 10.10 to our Amendment No. 1 to Registration Statement on Form S-1, filed with the SEC on March 19, 2014, SEC File No. 333-194192, and incorporated by reference here).
10.10#	Termination and License Agreement, dated May 24, 2013, between SCYNEXIS. Inc. and Merck Sharp & Dohme Corp. (Filed with the SEC as Exhibit 10.12 to our Amendment No. 1 to Registration Statement on Form S-1, filed with the SEC on March 19, 2014, SEC File No. 333-194192, and incorporated by reference here).
10.11*	SCYNEXIS, Inc. Amended and Restated 2015 Inducement Award Plan, as amended and restated. (Filed with the SEC as Exhibit 10.1 to our Quarterly Report on Form 10-Q, filed with the SEC on November 9, 2022, SEC File No. 001-36365, and incorporated by reference here).
10.12*	Form of Stock Option Grant Notice and Stock Option Agreement under the SCYNEXIS, Inc. 2015 Inducement Award Plan. (Filed with the SEC as Exhibit 10.34 to our Registration Statement on Form S-1, filed with the SEC on April 9, 2015, SEC File No. 333-203314, and incorporated by reference here).
10.13*	Employment Agreement, effective June 1, 2015, between SCYNEXIS, Inc. and David Angulo (Filed with the SEC as Exhibit 10.24 to our Annual Report on Form 10-K, filed with the SEC on March 7, 2016, SEC file No. 001-36365, and incorporated by reference here).
10.14*	Employment Agreement, dated February 5, 2015, between SCYNEXIS, Inc. and Dr. Marco Taglietti. (Filed with the SEC as Exhibit 10.27 to our Annual Report on Form 10-K, filed with the SEC on March 30, 2015, SEC File No. 001-36365, and incorporated by reference here).
10.15	Patent Assignment, dated January 28, 2014, between SCYNEXIS, Inc. and Merck Sharpe & Dohme Corp. (Filed with the SEC as Exhibit 10.28 to our Registration Statement on Form S-1, filed with the SEC on February 27, 2014, SEC File No. 333-194192, and incorporated by reference here).
10.16#	Exclusive License Agreement, dated October 29, 2014, between SCYNEXIS, Inc. and Waterstone Pharmaceutical (HK Limited). (Filed with the SEC as Exhibit 10.32 to our Annual Report on Form 10-K, filed with the SEC on March 30 2015, SEC File No. 001-36365, and incorporated by reference here).
10.17#	Amendment to Termination and License Agreement, dated December 11, 2014, between SCYNEXIS, Inc. and Merck Sharp & Dohme Corp. (Filed with the SEC as Exhibit 10.33 to our Annual Report on Form 10-K, filed with the SEC on March 30, 2015, SEC File No. 001-36365, and incorporated by reference here).
10.18#	Second Amendment to License Agreement between SCYNEXIS, Inc. and Merck Sharp & Dohme Corp. dated December 21, 2016 (Filed with the SEC as Exhibit 10.30 to our Annual Report on Form 10-K, filed with the SEC on March 13, 2019, SEC file No. 001-36365, and incorporated by reference here).
10.19*	Amendment of Employment Agreement, effective April 18, 2016, between SCYNEXIS, Inc. and Marco Taglietti. (Filed with the SEC as Exhibit 10.2 to our Quarterly Report on Form 10-Q, filed with the SEC on May 9, 2016, SEC File No. 001-36365, and incorporated by reference here).
10.20*	Amendment of Employment Agreement, effective April 18, 2016, between SCYNEXIS, Inc. and David Angulo. (Filed with the SEC as Exhibit 10.3 to our Quarterly Report on Form 10-Q, filed with the SEC on May 9, 2016, SEC File No. 001-36365, and incorporated by reference here).

10.21	Amendment to the Development, License and Supply Agreement, dated August 1st, 2013, between SCYNEXIS, Inc. and R-Pharm, CJSC (Filed with the SEC as Exhibit 10.1 to our Quarterly Report on Form 10-Q, filed with the SEC on November 11, 2019, SEC file No. 001-36365, and incorporated by reference here).
10.22	Additional Agreement No. 2 to the Development, License and Supply Agreement, dated August 1st, 2013, between SCYNEXIS, Inc. and R-Pharm, CJSC (Filed with the SEC as Exhibit 10.2 to our Quarterly Report on Form 10-Q, filed with the SEC on November 11, 2019, SEC file No. 001-36365, and incorporated by reference here).
10.23	Additional Agreement No. 3 to the Development, License and Supply Agreement, dated August 1st, 2013, between SCYNEXIS, Inc. and R-Pharm, CJSC (Filed with the SEC as Exhibit 10.3 to our Quarterly Report on Form 10-Q, filed with the SEC on November 11, 2019, SEC file No. 001-36365, and incorporated by reference here).
10.24	Third Amendment to Termination and License Agreement between SCYNEXIS, Inc. and Merck Sharp & Dohme Corp. dated January 5, 2018 (Filed with the SEC as Exhibit 10.1 to our Quarterly Report on Form 10-Q, filed with the SEC on May 8, 2019, SEC file No. 001-36365, and incorporated by reference here).
10.25*	Non-Employee Director Compensation Policy (Filed with the SEC as Exhibit 10.1 to our Form 10-Q, filed with the SEC on August 15, 2022, SEC File No. 001-36365, and incorporated by reference here).
10.26	Senior Convertible Note Purchase Agreement, dated as of March 7, 2019, among SCYNEXIS, Inc., as Issuer, Puissance Capital Management, as the Investor (Filed with the SEC as Exhibit 10.1 to our current report on Form 8-K filed with the SEC on March 8, 2019, SEC File No 001-36365 and incorporated by reference here).
10.27	Common Stock Purchase Agreement, dated April 10, 2020, between SCYNEXIS, Inc. and Aspire Capital Fund, LLC (Filed with the SEC as Exhibit 10.1 to our Form 8-K, filed with the SEC on April 13, 2020, SEC File No. 001-36365, and incorporated by reference here).
10.28	Senior Convertible Note Purchase Agreement, dated as of April 9, 2020, among SCYNEXIS, Inc., as Issuer, Puissance Life Science Opportunities Fund IV, as the Investor, (including the form of Note attached thereto as Exhibit A). (Filed with the SEC as Exhibit 10.1 to our Form 8-K, filed with the SEC on April 9, 2020, SEC File No. 001-36365, and incorporated by reference here).
10.29	Fourth Amendment to Termination and License Agreement between SCYNEXIS, Inc. and Merck Sharp & Dohme Corp. dated December 2, 2020.
10.30#	Exclusive License and Collaboration Agreement, made as of February 11, 2021, by and between SCYNEXIS, Inc., Hansoh (Shanghai) Health Technology Co., Ltd. and Jiangsu Hansoh Pharmaceutical Group Company Limited (Filed with the SEC as Exhibit 10.1 to our Form 10-Q, filed with the SEC on May 17, 2021, SEC File No. 001-36365, and incorporated by reference here).
10.31#	Master Services Agreement, effective as of February 4, 2021, by and between SCYNEXIS, Inc. and Amplity, Inc. (Filed with the SEC as Exhibit 10.2 to our Form 10-Q, filed with the SEC on May 17, 2021, SEC File No. 001-36365, and incorporated by reference here).
10.32	Loan and Security Agreement, dated May 13, 2021, among the Company, Hercules Capital Inc., and Silicon Valley Bank (Filed with the SEC as Exhibit 10.1 to our Form 10-Q, filed with the SEC on August 16, 2021, SEC File No. 001-36365, and incorporated by reference here).
10.33#	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the Amended and Restated 2015 Inducement Award Plan.(Filed with the SEC as Exhibit 10.2 to our Form 10-Q, filed with the SEC on November 9, 2022, SEC File No. 001-36365, and incorporated by reference here).
10.34#	Form of Restricted Stock Unit Grant Notice and Award Agreement under the 2014 Equity Incentive Plan (Filed with the SEC as Exhibit 10.1 to our Form 8-K, filed with the SEC on February 8, 2022, SEC File No. 001-36365, and incorporated by reference here).
10.35	Controlled Equity OfferingSM Sales Agreement, dated May 17, 2021, between SCYNEXIS, Inc. and Cantor Fitzgerald & Co. (Filed with the SEC as Exhibit 1.1 to our Current Report on Form 8-K, filed with the SEC on May 18, 2021, SEC File No. 001-36365, and incorporated by reference here).
10.36	Controlled Equity OfferingSM Sales Agreement, dated May 17, 2021, between SCYNEXIS, Inc. and Ladenburg Thalmann & Co. Inc. (Filed with the SEC as Exhibit 1.2 to our Current Report on Form 8-K, filed with the SEC on May 18, 2021, SEC File No. 001-36365, and incorporated by reference here).

10.37	Employment Agreement, dated May 10, 2021, between SCYNEXIS, Inc. and Christine Coyne (Filed with the SEC as Exhibit 10.1 to our Annual Report on Form 10-Q, filed with the SEC on May 12, 2022, SEC File No. 001-36365, and incorporated by reference here).
10.38*	Separation Agreement, dated October 20, 2022, between SCYNEXIS, Inc. and Marco Taglietti.
10.39*	Employment Agreement, dated January 1, 2023, between SCYNEXIS, Inc. and David Angulo.
10.40*	Employment Agreement, dated October 24, 2022, between SCYNEXIS, Inc. and Ivor Macleod.
23.1**	Consent of Independent Registered Public Accounting Firm.
24.1**	Power of Attorney (see Signature page).
31.1**	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a)
31.2**	Certification of Chief Financial Officer pursuant to Rule 13(a)-14(a)/15d-14(a)
32.1***	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as Adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Schema Linkbase Document
101.CAL	XBRL Taxonomy Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Labels Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

Portions of this exhibit have been omitted (a) pursuant to a request for confidential treatment, which portions were omitted and filed separately with the Securities and Exchange Commission or (b) because it is both (i) not material and (ii) is the type of information that SCYNEXIS, Inc. treats as private or confidential.
* Designates management contract or compensatory plan or arrangement.
** Filed herewith.
*** Furnished herewith.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SCYNEXIS, INC.

By: /s/ David Angulo, M.D.
David Angulo, M.D.
Chief Executive Officer
(Principal Executive Officer)

Date: March 29, 2023

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David Angulo, M.D. and Scott Sukenick, as his or her true and lawful attorney-in-fact and agent, with full power of substitution for him or her, and in his or her name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, and any of them or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ David Angulo, M.D. David Angulo, M.D.	Chief Executive Officer (Principal Executive Officer)	March 29, 2023
/s/ Ivor Macleod Ivor Macleod	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2023
/s/ Guy Macdonald Guy Macdonald	Director	March 29, 2023
/s/ David Hastings David Hastings	Director	March 30, 2023
/s/ Steven C. Gilman, Ph.D. Steven C. Gilman, Ph.D.	Director	March 30, 2023
/s/ Ann F. Hanham, Ph.D. Ann F. Hanham, Ph.D.	Director	March 29, 2023
/s/ Armando Anido Armando Anido	Director	March 30, 2023
/s/ Brian Philippe Tinmouth Brian Philippe Tinmouth	Director	March 29, 2023