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, 2019

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 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 28, 2019 was $70,456,262. Excludes 736,725 shares of the registrant's Common Stock held by executive officers and directors outstanding at June 28, 2019. 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, 2020, there were 97,417,224 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 2020 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, 2019.

SCYNEXIS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2019

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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," "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.

ITEM 1. BUSINESS

Overview

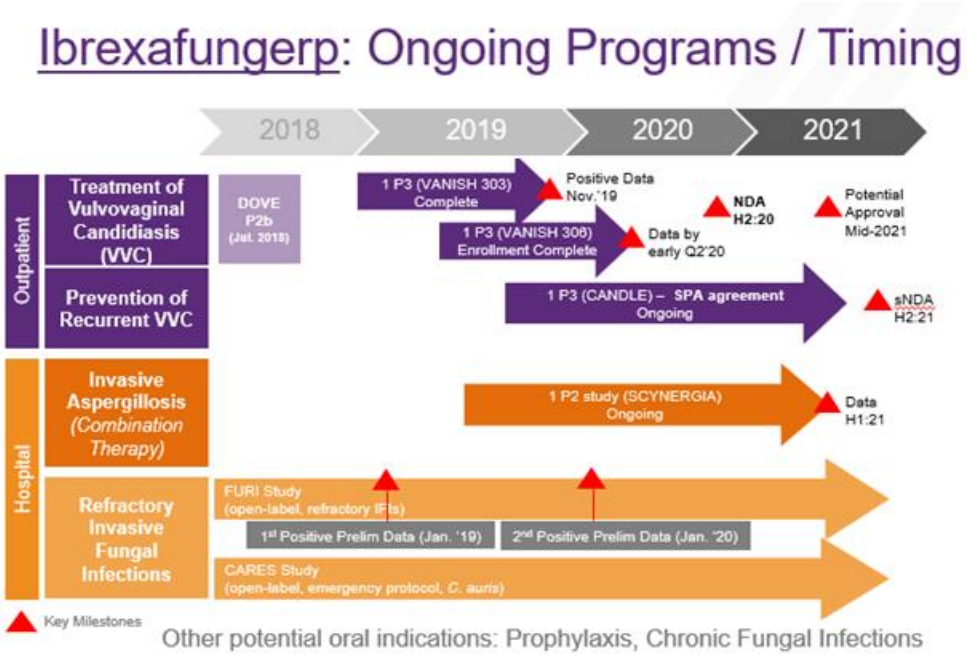
SCYNEXIS, Inc. is pioneering a new class of antifungal medicines to help millions of patients worldwide in need of new options to overcome and prevent difficult-to-treat and drug resistant infections. Our lead candidate, ibrexafungerp, is a broad-spectrum, intravenous (IV)/oral agent in late stage development for multiple indications, ranging from the treatment of vaginal yeast infections in the community setting to life-threatening invasive fungal infections in hospitalized patients.

Ibrexafungerp, the first agent in a novel antifungal class called triterpenoids, is a structurally distinct glucan synthase inhibitor that has shown *in vitro* and *in vivo* activity against a broad range of human fungal pathogens such as *Candida* and *Aspergillus* species, including multidrug-resistant strains, as well as *Pneumocystis, Coccidioides, Histoplasma* and *Blastomyces* species. *Candida* and *Aspergillus* species 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* and *in vivo* studies. The U.S. Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the formulations of ibrexafungerp for the indications of vulvovaginal candidiasis (VVC) (including 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. These designations may provide us with additional market exclusivity and expedited regulatory paths. Recognizing that our agent belongs to a new class of antifungals, the World Health Organization's International Non-Proprietary Name group created a new naming stem ("-fungerp") and selected the name "ibrexafungerp" for SCY-078 in July 2018, and the United States Adopted Names Council (USAN Council) adopted "ibrexafungerp" as a USAN in February 2019.

VVC, commonly known as "vaginal yeast infection," is the second-most common cause of vaginitis, affects 75% of women worldwide, and is usually caused by *Candida* species. IA and IC, caused by *Aspergillus* and various *Candida* species, respectively, are serious fungal infections that are reported to be among the leading causes of infection-caused death in immunocompromised patients. Refractory invasive fungal infections (rIFIs) are very severe fungal infections, often caused by multidrug-resistant pathogens, including *Candida auris*, resulting in high mortality rates.

Our Platform of Indications

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 indications for oral ibrexafungerp, currently in late stage development for VVC, as well as the upcoming anticipated New Drug Application (NDA) submissions:



Vaginal Yeast Infections — Our most advanced stage of clinical development, targeting both treatment of VVC and prevention of recurrent VVC.

The Phase 3 registration program for the treatment of VVC and prevention of recurrent VVC comprises three multi-center, randomized, double-blind, placebo-controlled trials designed to demonstrate superiority of oral ibrexafungerp vs. placebo, as detailed below:

- *Treatment of VVC (VANISH Phase 3 Program)*

In November 2019, we announced positive top-line results from our first Phase 3 study (VANISH-303). Specifically, ibrexafungerp achieved superiority over placebo at a highly statistically significant level ($p \leq 0.001$) for the primary endpoint and key study endpoints required for regulatory approval of the VVC indication.

The VANISH-303 study evaluated the safety and efficacy of the single-day, oral 600mg dose of ibrexafungerp (two doses of 300mg 12 hours apart), compared to placebo. Patients with a diagnosis of VVC were randomized to ibrexafungerp or placebo in a 2:1 ratio. Similar to the design of the Phase 2b DOVE study, the primary endpoint of each trial is clinical cure rate, defined as the complete resolution of all signs and symptoms (S&S), at the Test-of-Cure (TOC) visit (Day 10). Secondary endpoints include mycological eradication and change in S&S scores compared to baseline at both Day 10 and at the follow-up (FU) visit (Day 25).

The VANISH-303 study was designed following the 2016 "Vulvovaginal Candidiasis: Developing Drugs for Treatment, Guidance for Industry" by the FDA. The study was conducted at 28 centers in the U.S. and enrolled 376 patients, with enrollment completed several months faster than anticipated. To be eligible for this study, patients needed to present with an acute episode of VVC with S&S score of four or greater on a scale of zero (no S&S) to 18 (maximum severity). Primary efficacy analyses were conducted in the modified-intent-to-treat (mITT) population, comprised of patients with culture confirmed *Candida* spp. infection at baseline who received at least one dose of study treatment. The characteristics for both groups were evenly balanced at baseline, including the severity of the vaginal infection.

The observed clinical cure for ibrexafungerp was 50.5%, showing highly statistically significant superiority to placebo ($p=0.001$). Mycological eradication (secondary endpoint) at TOC in ibrexafungerp patients was 49.5%, also showing superiority to placebo ($p<0.001$). The VANISH-303 ibrexafungerp efficacy results confirm results observed in the Phase 2b DOVE study and achieve the superiority versus placebo required for regulatory approval.

Clinical improvement (score of 0 or 1) at TOC, another secondary endpoint that is a clinically relevant assessment of treatment response, was achieved in 64.4% of ibrexafungerp patients ($p<0.001$ against placebo). This result is also consistent with findings observed in the Phase 2b DOVE study.

Oral ibrexafungerp was generally safe and well tolerated. Severe and serious adverse events (AEs) were rare, with more cases reported in the placebo group than the ibrexafungerp group, and there were no drug-related serious AEs. The majority of Treatment-Emergent AEs (TEAEs) observed at a higher frequency in the ibrexafungerp group were gastrointestinal (GI) in nature, with the three most common GI events (diarrhea/loose stool, nausea and abdominal pain) occurring at rates of 25.5%, 16.6%, and 7.3%, respectively, similar to the rates seen in the Phase 2b DOVE study. These events were predominantly regarded as mild, of short-duration and did not lead to discontinuation, confirming the favorable tolerability profile of the single-day 600mg dose regimen of oral ibrexafungerp previously observed.

In February 2020, we announced completion of patient enrollment, ahead of schedule, in our second Phase 3 study (VANISH-306) and re-confirmed that we anticipate top-line data early in the second quarter of 2020. The VANISH-306 study, with identical design to VANISH-303, was conducted at 42 centers in the U.S. and Europe and enrolled 455 patients. As with VANISH-303, enrollment in VANISH-306 was also completed several months faster than anticipated.

We expect these two pivotal studies to provide the safety and efficacy data to support an NDA for ibrexafungerp for the treatment of VVC, with submission to the FDA planned in the second half of 2020.

- *Prevention of Recurrent VVC*

In July 2019, we announced that we reached an agreement with the FDA under a Special Protocol Assessment (SPA) on the design, trial population, endpoints and statistical analysis of the pivotal Phase 3 clinical trial of oral ibrexafungerp for the prevention of recurrent VVC (the CANDLE study). This SPA provides agreement with the FDA that the Phase 3 protocol design adequately addresses efficacy objectives that, if met, would form the primary basis of a regulatory submission for approval of oral ibrexafungerp for the prevention of recurrent VVC, an indication with no FDA-approved therapies.

Enrollment is ongoing in the CANDLE study, a Phase 3, multi-center, randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of oral ibrexafungerp compared to placebo in women with recurrent VVC (defined as three or more episodes of VVC in the past 12 months, including the episode at screening). The primary endpoint of the study is efficacy as measured by the percentage of patients with no recurrences of VVC, up through their TOC evaluation at week 24. Secondary endpoints of the study include evaluation of VVC recurrences at other time points, time to first recurrence, mycological eradication and quality of life assessments. All patients in the CANDLE study will initially receive three doses of oral fluconazole to treat their acute VVC episode present at screening. Patients who respond to oral fluconazole for their acute VVC episode will be enrolled in the prevention of recurrence phase of the study and randomized to oral ibrexafungerp (300mg BID for one day) or placebo, given once per month for a total of six treatment days. Patients who fail to sufficiently respond to fluconazole treatment for their acute VVC episode will be included in a nested open-label sub-study, in which they will be offered a single day of oral ibrexafungerp treatment (300mg BID) for their unresolved VVC infection. The CANDLE study, which is being conducted in female patients age 12 years and older living with recurrent VVC, is expected to enroll approximately 320 subjects from approximately 50 global centers, many of which had enrolled patients in our VANISH Phase 3 program. Pending successful completion of this trial, we anticipate top-line data and the submission of a supplemental NDA for the prevention of recurrent VVC in the second half of 2021.

Refractory Invasive Fungal Infections—Potential for streamlined development pathway.

Enrollment is ongoing in our rIFI program, which comprises two open-label Phase 3 studies (FURI and CARES) designed to support a potential future NDA submission through the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD).

To date, we have announced the interim results of the first 41 patients of the FURI study following analysis by a Data Review Committee (DRC), an independent expert panel. The DRC assessed the efficacy of oral ibrexafungerp in a second cohort of 21 treated patients from the FURI study (reported in January 2020). This second interim analysis was limited to only patients who had completed treatment by the end of October 2019, and so did not include enrolled patients still on therapy who had not yet reached the point of clinical assessment. Together with the initial 20 patients reported in January 2019, the dataset consists of 41 patients analyzed to date. Efficacy was consistent across both interim analyses, as oral ibrexafungerp showed clinical benefits in 83% of patients (34 out 41), with 23 patients achieving a complete or partial response and 11 patients a stable disease response. Of the 41 treated patients, only six did not respond to ibrexafungerp treatment and one patient was considered indeterminate. The 41 patients in the aggregate analysis suffered from a variety of severe conditions, including candidemia, intra-abdominal abscesses, esophageal candidiasis, oropharyngeal candidiasis, and bone infections. *Candida glabrata* and *Candida krusei*, two highly resistant organisms, were reported in approximately 70% of the cases. Ibrexafungerp treatment ranged from five to 90 days, with a mean duration of 37.1 days.

Oral ibrexafungerp was generally safe and well-tolerated, with gastrointestinal events side effects as the most common treatment-related adverse events. One patient with an ongoing fungal infection died while on study drug due to an underlying condition. The death was considered not drug-related and there were no safety signals warranting changes to the study.

In October 2019, we expanded the FURI protocol to include a broader range of rIFIs, extended the maximum allowed treatment duration with ibrexafungerp from 90 days to up to 180 days as needed for chronic conditions, based on favorable preclinical toxicology studies, and also made ibrexafungerp available as a combination therapy with SoC for selected subjects. Under the amended study design, patients with aspergillosis, coccidioidomycosis, histoplasmosis, blastomycosis and infections caused by other emerging fungi including yeasts and molds are now eligible for enrollment along with those suffering from *Candida* infections.

We also are enrolling patients in the CARES study, a global, open-label study of oral ibrexafungerp for the treatment of *Candida auris* infections. *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 resulting in an NDA submission based on streamlined development. The LPAD was established under the 21st Century Cures Act of 2016, and FDA draft guidance issued in June 2018 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. We plan to continue to advance enrollment in the FURI and CARES studies, both in the U.S. and globally. Positive clinical findings from these 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 Pulmonary Aspergillosis—Ibrexafungerp in combination with standard of care may represent a significant opportunity to improve outcomes for this high-mortality infection.

Based on promising pre-clinical data from combination use of ibrexafungerp with SoC vs. *Aspergillus* spp., we are conducting a Phase 2 study (SCYNERGIA study) of oral ibrexafungerp in combination with voriconazole (SoC) 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. SoC.

IV Development Program

While oral ibrexafungerp is progressing as a potential valuable option to treat hospital-based invasive fungal infections, as shown by the two preliminary results from the FURI study, we continue the development of the intravenous liposomal formulation of ibrexafungerp and will provide further updates on this program in the future.

Key Milestones

We are focused on pursuing the following milestones through the second half of 2021:

- to provide top-line data of the Phase 3 VANISH-306 study early in the second quarter of 2020;
- to submit an NDA for the treatment of VVC in the second half of 2020, with a potential approval by the FDA in mid-2021;
- to provide top-line data of the Phase 2 SCYNERGIA study in the first half of 2021;
- to provide top-line data of the Phase 3 CANDLE study in the second half of 2021, to allow for a potential supplemental NDA submission for the prevention of recurrent VVC in the second half of 2021;
- to continue to advance enrollment in both the FURI and CARES studies with a potential new preliminary data review when adequate enrollment levels have been reached; and
- to maintain an ongoing dialogue with potential commercial partners in the U.S. and outside of the U.S.

Our Strategy

Key elements of our strategy include:

- to advance development of ibrexafungerp and obtain regulatory approval in major commercial markets for our key initial indications: treatment and prevention of vaginal yeast infections, salvage therapy for certain rIFIs, IA, and IC;

- to commercialize ibrexafungerp for selected indications in the U.S. through a dedicated commercial and sales team, and/or through potential partnerships;
- to contract with commercial partners to develop and commercialize ibrexafungerp outside of the U.S.;
- to assess external opportunities to expand our clinical pipeline;
- to assess external opportunities to obtain non-dilutive third-party funding to expand our clinical indications; and
- to leverage our strong scientific team to pursue the development of other internal proprietary compounds.

Market Opportunity

Vaginal Yeast Infections

Vaginal yeast infections affect approximately 70%-75% of women at least once in their lifetime, with 40-50% of these women experiencing more than one episode. We estimate approximately 6-8% of women experience recurrent infections (three to four or more episodes in one year). Episodes may be split in two main categories:

- *Uncomplicated cases.* These are sporadic mild-to-moderate infections typically caused by *C. albicans* in a normal host. They represent the majority of the VVC episodes; and
- *Complicated cases.* These represent the remaining episodes and include: severe infections, recurrent cases, infections caused by non-*albicans Candida* spp., fluconazole-resistant infections, fluconazole intolerant and non-responder cases, infections in women of child-bearing age concerned about fluconazole's reported embryo/fetal toxicities, and/or observed in an abnormal host.

Vaginal yeast infections can be associated with substantial morbidity, including significant genital discomfort, reduced sexual pleasure, psychological distress and loss of productivity. Diagnosis and treatment of VVC, together with lost productivity, is estimated to cost $1.0 billion per year in the U.S.

Current treatments for vaginal yeast infections include over-the-counter (OTC) (clotrimazole, miconazole, and others) and prescription (teraconazole) topical azole antifungals and the use of the prescription oral azole antifungal, fluconazole. Fluconazole is the only orally-administered antifungal currently approved for treatment of VVC in the U.S., with a therapeutic cure rate of 55% as reported in its label. Uncomplicated VVC cases are often effectively treated with topical agents and/or with one to three doses of oral fluconazole. However, many cases of VVC are not fully addressed by oral fluconazole and patients are left with limited options. In addition, there are no oral alternatives for VVC patients who do not respond to or tolerate fluconazole or patients of child-bearing age concerned about fluconazole's reported embryo/fetal toxicities, and there are no FDA-approved products for the prevention of recurrent VVC.

We believe that the regulatory path toward approval in VVC is straightforward and has a high chance of technical success. With the strong clinical evidence observed in our Phase 2b DOVE and VANISH-303 studies, we believe that ibrexafungerp, if approved, would provide a new oral non-azole option for millions of women currently underserved by existing therapies.

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.

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* species, including multidrug-resistant strains, as well as *Pneumocystis, Coccidioides, Histoplasma* and *Blastomyces* species. Additionally, ibrexafungerp has shown *in vitro* and *in vivo* activity against multidrug-resistant organisms such as *Candida auris*

and synergistic/additive activity in combination with isavuconazole against *Aspergillus* strains. 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 *Candida* species 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;
- well tolerated with over 900 subjects exposed;
- 20-hour half-life with a low risk of drug-drug interactions; and
- lack of teratogenicity in animal studies.

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

- complicated cases of vaginal yeast infections, including recurrent infections;
- invasive aspergillosis (including resistant infections);
- refractory invasive fungal infections; and
- invasive candidiasis (including resistant infections).

In the future, we 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.

Given our stage of development, we have not yet established a commercial organization or distribution capabilities and we are in the process of assessing our global commercial strategy.

For the treatment and prevention of vaginal yeast infections, we anticipate that prescribing physicians will mostly be obstetricians, gynecologists, and nurse practitioners. For these indications, we intend to form our own focused field force to target physicians in the U.S. Outside of the U.S., subject to obtaining necessary marketing approvals, we will likely seek to commercialize ibrexafungerp through distribution or other collaboration arrangements.

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. For these indications, we intend to form our own focused hospital-based field force to target physicians in the U.S. Outside of the U.S., subject to obtaining necessary marketing approvals, we will likely seek to commercialize ibrexafungerp through distribution or other collaboration arrangements.

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), recently approved in the U.S. and other global markets and marketed by Astellas in the U.S.;

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

Further, we expect that product candidates currently in clinical development may represent significant competition, if approved. These include the azole Oteseconazole (VT-1161) being developed by Mycovia Pharmaceuticals, Inc., formerly Viamet Pharmaceuticals, Inc. (assets acquired by NovaQuest Capital Management, LLC), the long-acting IV echinocandin Rezafungin (CD101) being developed by Cidara Therapeutics, Inc., 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 sparse competitive marketplace, the unmet medical need, and the 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, price, 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.

Our commercial opportunity could be reduced or eliminated if our 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 may develop. Our competitors also may obtain FDA, or other regulatory, approval for their products more rapidly than we may obtain approval for ours. In addition, our ability to compete 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 kilogram quantities of drug substance and of producing drug product to support ongoing and planned clinical trials. 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 ongoing and planned clinical trials and for commercial production.

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 launch, we expect cost of goods for ibrexafungerp to be similar to that of other small molecule drugs. We have negotiated agreements with suppliers to produce both drug product and drug substance for our current needs. In the future, we plan to validate the process with selected vendors and secondary suppliers to establish a secure supply chain that could enable commercialization.

We estimate our supplies on hand for the oral formulation of ibrexafungerp are sufficient to supply our ongoing and planned clinical trials. Manufacture of additional supplies of ibrexafungerp drug substance is planned to support any further optimization of either the oral or IV formulations, if needed. Additional batches of both oral and IV ibrexafungerp drug product will be manufactured as needed to support the subsequent stages of our clinical development plan.

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. The third-party vendors that currently manufacture clinical supplies to support our ongoing clinical studies have the necessary capabilities and are in compliance with cGMP appropriate for the current stage of development.

The third-party vendors we will select to support our manufacturing and supply program both for future late-stage development and commercial readiness activities will 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:

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 is eligible to receive milestones upon initiation of a Phase 3 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 2018, 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. Except as described above, all other terms and provisions of the license agreement remain in full force and effect. 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.

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. We recognized revenue from this upfront payment of $0.1 million and $0.3 million for the years ended December 31, 2019 and 2018, respectively.

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.

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 Qualifying 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.

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.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States our activities are potentially 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 (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, 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.

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 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. 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.

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, 2020, we are the owner of nine issued U.S. patents and 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 2035. Of these patents, three U.S. patent relates to ibrexafungerp. We are actively pursuing four U.S. patent applications and many non-U.S. patent applications in multiple jurisdictions worldwide.

Ibrexafungerp is protected by an issued composition of matter patent(U.S. Patent No. 8,188,085) in the United States, which expires in 2030, and we will have ten to twelve years of regulatory exclusivity in the U.S. Based on our current development plan, we believe that an additional term of up to five years for the ibrexafungerp composition of matter U.S. patent may result from the patent term extension provision of the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). The composition of matter patent has been granted in 63 countries and is pending in 16 other countries. Two patents related to ibrexafungerp salts and polymorphs, including the citrate salt currently under development, have issued, with expiration expected in 2035. 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 and uses up to 2039. 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, 2020, we had 27 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.

Risks Relating to Our Financial Condition and Need for Additional Capital

We have never been profitable, we have no products approved for commercial sale, and to date we have not generated any 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 $53.7 million for the year ended December 31, 2019. As of December 31, 2019, we had an accumulated deficit of approximately $271.4 million. On a prospective basis, our strategic focus, along with the commitment of our financial resources, will be directed towards the development of ibrexafungerp, our lead product candidate. We had cash and cash equivalents and short-term investments of $48.4 million as of December 31, 2019. Based upon our existing operating plan, we believe that our existing cash and cash equivalents and short-term investments, and the sale of a portion of our New Jersey NOLs, will enable us to fund our operating requirements past a potential Prescription Drug User Fee Act (PDUFA) date in mid-2021 for the treatment of VVC when we expect the FDA to complete the review of the NDA and potentially approve ibrexafungerp for the treatment of VVC, although there can be no assurances that we will be able to continue our operations on a long-term basis. We have suffered substantial losses from operations since inception and will require additional financing.

We expect to continue to incur significant expenses and increasing 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:

- continue the development of ibrexafungerp for treatment of multiple indications;
- conduct ongoing and initiate new clinical trials for ibrexafungerp;
- seek marketing approvals for ibrexafungerp;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- 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, an adverse effect on our stockholders' equity, financial position and working capital.

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 developing ibrexafungerp, which are difficult for us to predict;
- any delays in regulatory review and approval of ibrexafungerp;

- delays in the timing of submission of a new drug application, or NDA, as well as commencement, enrollment and the timing of clinical testing, of ibrexafungerp or any other product candidates we may seek to develop;
- our ability to commercialize product candidates, both in the United States and overseas, if we are able to obtain regulatory approval to do so;
- the costs associated with obtaining and maintaining regulatory approval and ongoing company compliance and product compliance for ibrexafungerp;
- market acceptance of ibrexafungerp and any future product candidates we may seek to develop;
- 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. Based upon our existing operating plan, we believe that our existing cash and cash equivalents and short-term investments, and the sale of a portion of our New Jersey NOLs, will enable us to fund our operating requirements past a potential PDUFA date in mid-2021 for the treatment of VVC when we expect the FDA to complete the review of the NDA and potentially approve ibrexafungerp for the treatment of VVC; provided, however, that changing circumstances may cause us to consume cash more rapidly than we currently anticipate. 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 ibrexafungerp and any future 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 future 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 ibrexafungerp and any future product candidates we may seek to develop;
- seek strategic alliances for research and development programs at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms our rights to any product candidates that we otherwise would seek to develop or commercialize ourselves.

If we are required to conduct additional fundraising activities and we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects.

Our operating activities may be restricted as a result of covenants related to the indebtedness under our senior convertible notes and we may be required to repay the notes in an event of default, which could have a materially adverse effect on our business.

On March 7, 2019, we entered into a Note Purchase Agreement with Puissance, pursuant to which we issued and sold to Puissance $16 million of our 6.0% senior convertible notes due 2025. The Note Purchase Agreement provides, among other

restrictions, that so long as at least 25% of the initial aggregate principal amount of the notes remain outstanding, we will not incur indebtedness that is senior in right of payment to the notes, other than certain permitted indebtedness, until after data from our Phase 3 study in acute VVC has demonstrated that it has met its primary endpoint with statistical significance (such data expected in the first half of 2020). Our business may be adversely affected by these restrictions on our ability to operate our business.

Additionally, we may be required to repay the outstanding notes if an event of default occurs under the Note Purchase Agreement. Under the Note Purchase Agreement, 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 Agreement, 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.

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, and without regulatory approval we will not be able to market ibrexafungerp. Regulatory approval is a lengthy, expensive and uncertain process.

Our ability to generate significant revenue related to ibrexafungerp sales will depend on the successful development and regulatory approval of ibrexafungerp. We expect that the earliest that we could obtain regulatory approval of ibrexafungerp and commence commercialization of ibrexafungerp will be several years from now, if at all.

We currently have no products approved for sale and we cannot guarantee that we will ever have 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 from the FDA. We have not submitted an NDA for ibrexafungerp. 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 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 the recent emergence and spread of COVID-19, a coronavirus, 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 have limited experience in designing clinical trials and 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 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 limited experience in conducting clinical trials and have never submitted an NDA before, and we may be unable to do so for ibrexafungerp or any future product candidate we may seek to develop.

Merck completed seven Phase 1 clinical trials of ibrexafungerp and we have completed nine Phase 1 clinical trials, three Phase 2 trials, and have initiated five Phase 3 trials which are ongoing. We are planning to conduct additional Phase 1, Phase 2, and Phase 3 clinical trials of ibrexafungerp. 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 five Phase 3 clinical trials, and we have never submitted an NDA. Consequently, we may be unable to successfully and efficiently execute and complete these planned clinical trials in a way that is acceptable to the FDA and leads to an NDA submission, acceptance and approval of 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 ibrexafungerp 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 ibrexafungerp 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 ibrexafungerp 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 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.

Current treatment regimens for invasive fungal infections typically involve initial administration of treatments as an IV infusion, with a switch to an oral formulation of the same or a similar medication to complete the course of treatment on an out-patient basis. We believe that providing both the IV and oral formulations will be beneficial to doctors who prefer to start treatment of patients in a hospital setting with an IV therapy and then switch them to an oral formulation of the same medication. If we are unable to successfully develop and achieve regulatory approval for either the oral or IV formulation of ibrexafungerp, our lead product candidate may not achieve, or may be delayed in achieving, 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.

It is impossible to predict when or if ibrexafungerp or any other product candidate we may seek to develop will prove effective or safe or will receive marketing approval. 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 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.

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. If the FDA does not permit us to initiate new clinical studies with our IV formulation, we will not be able to develop and commercialize an IV formulation of ibrexafungerp, which would harm our business prospects.

Preclinical findings in the future could trigger the need to evaluate or monitor for specific potential safety concerns in clinical trials. The results of future 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.

Even if ibrexafungerp or any future product candidate we may seek to develop receives marketing approval, we or others may subsequently identify undesirable or unacceptable side effects caused by these products, in which case:

- regulatory authorities may require the addition of labeling statements, specific warnings, precautions, contraindications or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may have limitations on how we promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our current or potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of products.

We have never marketed a drug before, and if we are unable to establish an effective sales force and marketing infrastructure or enter into acceptable third-party sales and marketing or licensing arrangements, we may not be able to successfully commercialize ibrexafungerp and any future product candidates we may seek to develop.

We currently do not have any sales, distribution and marketing capabilities, the development of which will require substantial resources and will 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. In addition, we plan to enter into 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, 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 ibrexafungerp 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, price, lack of significant adverse side effects and convenience and ease of treatment. For example, ibrexafungerp 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 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. 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.

Because ibrexafungerp is not currently commercially available, we do not know the extent to which it will be able to obtain favorable coverage and adequate reimbursement from third-party payors if it is approved by the FDA. 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.

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, including the Affordable Care Act, or changes or repeal of the Affordable Care Act, 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 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 includes provisions to 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 imposes an annual tax on pharmaceutical manufacturers or importers who sell "branded prescription drugs." Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would replace or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 includes 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". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. Further, the Bipartisan Budget Act of 2018 (BBA) among other things, amends the Affordable Care Act, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole".

On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business. 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 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, at the federal level, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. On January 31, 2019, the HHS Office of Inspector General proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

We cannot predict what healthcare reform initiatives may be adopted in the future. 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 ibrexafungerp 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 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.

Even if ibrexafungerp or any other future product candidates we may seek to develop receive regulatory approval, we may still face future development and regulatory difficulties.

Even if regulatory approval is obtained for 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.

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 the foregoing requirements could result in 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 and civil monetary penalties law, including the federal civil False Claims Act, prohibit any person from 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. Pharmaceutical and other healthcare companies have also been prosecuted on other legal theories of Medicare and Medicaid fraud.

The federal Health Insurance Portability and Accountability Act of 1996 (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" that perform services for them, which involve the creation, use, maintenance or disclosure of, individually identifiable health information.

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 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 civil monetary penalties, exclusion of a company's products from reimbursement under government programs, integrity oversight and reporting obligations to resolve allegations of non-compliance with these laws, disgorgement, and criminal fines and imprisonment. 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 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.

We are dependent on other third-party collaborations to develop and commercialize product candidates we have outlicensed, and if our third-party collaborators are not successful in developing and commercializing product candidates we have outlicensed, we will not receive any revenue from these collaborations.

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 license agreements with R-Pharm to develop and commercialize ibrexafungerp in Russia. We are relying on these third parties to commercialize the compounds subject to the respective license agreements, and if they are not able to commercialize the compounds subject to the respective agreements, or determines not to pursue commercialization of the compounds, we will not receive any royalty payments under the agreements. If our third-party collaborators under these agreements and any future agreements we enter into do not perform under the agreements, or terminate the agreements, we will not receive the benefits we expect under the agreements.

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, we plan to establish collaborations for development and commercialization of product candidates and research programs. 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 productwe 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.

If ibrexafungerp is approved, the inability to manufacture sufficient commercial supplies of the drug product 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.

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.

There have been numerous changes to the patent laws and proposed changes to the rules of the USPTO, which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, in September 2011, President Obama signed the America Invents Act that codifies several significant changes to the U.S. patent laws, including, among other things, changing from a "first to invent" to a "first inventor to file" system, limiting where a patent holder may file a patent suit, replacing interference or "first to invent" proceedings with derivation proceedings and creating inter partes review and post-grant opposition proceedings to challenge the validity of patents after they have been issued. The effects of these changes are currently unclear as the USPTO only recently has adopted regulations implementing the changes, the courts have yet to address most of these provisions, and the applicability of the act and new regulations on specific patents and patent applications discussed herein have not been determined and would need to be reviewed.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market in the relevant country or region, which could have a material adverse effect on our business.

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, 2020, we had 27 employees. As we advance ibrexafungerp through preclinical studies, clinical trials and commercialization, 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 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.

U.S. and foreign privacy and data protection laws and regulations may impose additional liabilities on us.

U.S. federal and state privacy and data security laws and regulations regulate how we and our partners collect, use and share certain information. 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. State security breach notification laws, state health information privacy laws, and other state privacy laws also impose requirements regarding the collection, use, disclosure, and protection of personal information. In addition, in June 2018, California enacted the California Consumer Privacy Act of 2018 (CCPA) which became effective January 1, 2020. The CCPA gives California residents the right to access and require deletion of their personal information, the right to opt out of certain personal information sharing, and the right to detailed information about how their personal information is collected, used, and disclosed. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is

expected to increase data breach litigation. 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 information we collect about California residents. The CCPA has prompted a wave of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs, and adversely affect our business.

We may also be subject to or affected by foreign laws and regulations, including regulatory guidance, governing the collection, use, disclosure, security, transfer, and storage of personal data, such as information that we collect about patients in connection with clinical trials and our other operations abroad. The global legislative and regulatory landscape for privacy and data protection continues to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, result in liability, or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future.

For example, the EU implemented the General Data Protection Regulation (GDPR) a broad data protection framework that expands the scope of EU data protection law to include certain non-European Union entities that process the personal data of EU residents, including clinical trial data. The GDPR increases our compliance burden with respect to data protection, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and protect information about them. The processing of sensitive personal data, such as information about health conditions, leads to heightened compliance burdens under the GDPR and is a topic of active interest among EU regulators. In addition, the GDPR provides for breach reporting requirements, more robust regulatory enforcement and fines of up to the greater of 20 million euros or 4% of annual global revenue. The GDPR increases our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business.

A data security breach or other privacy violation that compromises the confidentiality, integrity or availability of the personal information of our clinical trials participants, collaborators or employees could harm our reputation, compel us to comply with U.S. or international breach notification laws, subject us to mandatory corrective action, and otherwise subject us to liability under U.S. or foreign laws and regulations. Data breaches or other security incidents could also compromise our trade secrets or other intellectual property. If we are unable to prevent such data security breaches and security incidents or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer reputational harm, financial loss or other regulatory penalties. In addition, such events can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented security measures designed to protect our information technology systems, such measures may not prevent such events.

Finally, it is possible that these privacy laws may be interpreted and applied in a manner that is inconsistent with our practices. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort, and proceedings against us by governmental entities or others. If we expand into other foreign countries and jurisdictions, we may be subject to additional privacy and data protection laws and regulations that may affect how we conduct business.

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 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 and any future product candidate we may seek to develop or any adverse development or perceived adverse development with respect to the FDA's review of that NDA or a foreign regulator's review of a similar applications;
- maintenance of our existing collaborations or ability to enter into new collaborations;
- our collaboration partners' election to develop or commercialize product candidates under our collaboration agreements or the termination of any programs under our collaboration agreements;
- any intellectual property infringement actions in which we or our licensors and collaboration partners may become involved;
- our ability to successfully develop and commercialize future product candidates;
- changes in laws or regulations applicable to future products;

- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- achievement of financial projections we may provide to the public;
- achievement of the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- changes in the structure of healthcare payment systems;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- legislation or regulation that mandates or encourages the use of generic products;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- general economic and market conditions and overall fluctuations in the U.S. equity markets;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future; and
- trading volume of our common stock.

In addition, companies trading in the stock market in general, and the Nasdaq Global Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

We may identify material weaknesses in our internal controls over financial reporting.

Maintaining effective internal controls over financial reporting is necessary for us to produce accurate consolidated financial statements on a timely basis. Management continues to devote significant time, attention, and resources to maintaining and improving our internal controls. We expect to continue to incur costs associated with implementing appropriate processes and internal controls, which could include new employee compensation costs and fees for additional audit and consulting services, which could negatively affect our financial condition and operating results.

The requirements associated with being a public company will continue to require significant company resources and management attention.

Section 404(a) of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting, and we are required to disclose material changes made in our internal controls and procedures on a quarterly basis. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act.

If we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to achieve effective internal control over financial reporting, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Stock Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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 due 2025. 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. The initial conversion rate is 739.0983 shares of common stock per $1,000 principal amount of convertible notes, which is equivalent to an initial conversion price of approximately $1.35 per share, and is subject to adjustment in certain events. 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. Subject to adjustment in the conversion rate, the number of shares that we may deliver in connection with a conversion of the convertible notes, including those delivered in connection with an interest make-whole payment, will not exceed a cap of 813 shares of common stock per $1,000 principal amount of convertible notes. To the extent holders of these notes convert the notes, our stockholders may experience substantial dilution.

Because we do not intend to declare cash dividends on our shares of common stock in the foreseeable future, stockholders must rely on appreciation of the value of our common stock for any return on their investment.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the future. As a result, we expect that only appreciation of the price of our common stock, if any, will provide a return to our investors for the foreseeable future. Investors seeking cash dividends should not invest in our common stock.

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.

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, 2020, there were approximately 60 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. 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 2019.

ITEM 6. SELECTED FINANCIAL DATA

This item is not applicable to smaller reporting companies.

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

Operating results for the year ended December 31, 2019, 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 a new class of antifungal medicines to help millions of patients worldwide in need of new options to overcome and prevent difficult-to-treat and drug resistant infections. Our lead candidate, ibrexafungerp, is a broad-spectrum, intravenous (IV)/oral agent in late stage development for multiple indications, ranging from the treatment of vaginal yeast infections in the community setting to life-threatening invasive fungal infections in hospitalized patients.

Ibrexafungerp, the first agent in a novel antifungal class called triterpenoids, is a structurally distinct glucan synthase inhibitor that has shown *in vitro* and *in vivo* activity against a broad range of human fungal pathogens such as *Candida* and *Aspergillus* species, including multidrug-resistant strains, as well as *Pneumocystis, Coccidioides, Histoplasma and Blastomyces* species. *Candida* and *Aspergillus* species 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* and *in vivo* studies. The U.S. Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the formulations of ibrexafungerp for the indications of vulvovaginal candidiasis (VVC) (including 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. These designations may provide us with additional market exclusivity and expedited regulatory paths. Recognizing that our agent belongs to a new class of antifungals, the World Health Organization's International Non-Proprietary Name group created a new naming stem ("-fungerp") and selected the name "ibrexafungerp" for SCY-078 in July 2018, and the United States Adopted Names Council (USAN Council) adopted "ibrexafungerp" as a USAN in February 2019.

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, and December 2019. We have received an aggregate of $173.7 million in net proceeds from the issuance of our common stock in these five offerings. Our principal source of liquidity is cash and cash equivalents and short-term investments, which totaled $48.4 million as of December 31, 2019. In addition, during the year ended December 31, 2019, we received net proceeds of $11.0 million under our ATM facility and in January 2020, we entered into an agreement with a third party to sell a portion of our unused New Jersey Net Operating Losses (NOLs) and research and development credits for $3.1 million.

We have incurred net losses since our inception, including the year ended December 31, 2019. As of December 31, 2019, our accumulated deficit was $271.4 million. We anticipate that we will continue to incur losses for at least the next several years. We will continue to incur research and development expenses as we continue to execute our research and drug development strategy and continue to incur selling, general and administrative expenses to support our public reporting company operations. 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, New Jersey Technology Business Tax Certificate Transfer (NOL) Program), strategic alliances and licensing or collaboration arrangements. We may offer shares of our common stock pursuant to our Form S-3 shelf registration statement filed with the SEC on August 31, 2018 and declared effective on September 14, 2018 (Shelf Registration), including the related at-the-market (ATM) facility entered into on August 31, 2018 with Cantor Fitzgerald & Co., or Cantor.

Components of Operating Results

Revenue

Revenue consists of the amortization of a non-refundable upfront payment received under our collaboration arrangement with R-Pharm. The R-Pharm arrangement and our revenue recognition policy is described within the "Critical Accounting Policies and Significant Judgments and Estimates" section below, as well as in Note 2 to our audited consolidated financial statements for the year ended December 31, 2019, included in this Form 10-K.

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 related 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 will continue to incur research and development expense for the foreseeable future as we continue our effort to develop ibrexafungerp, specifically for our Phase 3 VVC registration programs, and potentially to develop our other in-house product candidates or candidates we may acquire; 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, 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;
- the expense recognized for the extinguishment of debt.

Income Tax Benefit

Income tax benefit consists of U.S. federal and state income taxes. 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, 2018, we recognized $6.7 million in income tax benefit associated with the sale of our NOLs for $6.7 million.

Results of Operations for the Years Ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018, and period-to-period percentage change (dollars in thousands):

	Years Ended December 31,			
	2019	2018	Period-to-Period Change	
Revenue	$ 121	$ 257	$ (136)	(52.9)%
Operating expenses:				
Research and development	38,394	21,560	16,834	78.1 %
Selling, general and administrative	10,648	8,680	1,968	22.7 %
Total operating expenses	49,042	30,240	18,802	62.2 %
Loss from operations	(48,921)	(29,983)	(18,938)	63.2 %
Other expense (income):				
Loss on extinguishment of debt	1,045	—	1,045	—
Amortization of debt issuance costs and discount	1,171	428	743	173.6 %
Interest income	(805)	(967)	162	(16.8)%
Interest expense	986	1,626	(640)	(39.4)%
Other income	(538)	—	(538)	—
Warrant liabilities fair value adjustment	4,497	(11,866)	16,363	(137.9)%
Derivative liability fair value adjustment	(1,567)	—	(1,567)	—
Total other expense (income):	4,789	(10,779)	15,568	(144.4)%
Loss before taxes	(53,710)	(19,204)	(34,506)	179.7%
Income tax benefit	—	6,736	(6,736)	(100 %)
Net Loss	**$ (53,710)**	**$ (12,468)**	**$ (41,242)**	**330.8 %**

Revenue. For the years ended December 31, 2019 and 2018, revenue consisted of the amortization of a non-refundable upfront payment received under our collaboration arrangement with R-Pharm.

Research and Development. For the year ended December 31, 2019, research and development expenses increased to $38.4 million from $21.6 million for the year ended December 31, 2018. The increase of $16.8 million, or 78.1%, was primarily driven by a milestone payment made in 2019 to Merck upon initiation of the Phase 3 VVC registration study, an increase of $11.8 million in clinical development expense, an increase of $0.6 million in chemistry, manufacturing, and controls (CMC), an increase of $1.1 million in salary and personnel related costs, and a net increase of $1.0 million in other research and development expenses, offset in part by a decrease of $1.7 million in preclinical expenses.

The $11.8 million increase in clinical development expense for the year ended December 31, 2019, was primarily driven by an increase of $9.3 million in costs associated with the VANISH Phase 3 VVC program, an increase of $1.9 million in costs associated with the CANDLE Phase 3 study, an increase of $0.9 million in expense associated with our SCYNERGIA Phase 2 study, an increase of $1.1 million in expense associated with two drug-drug interaction clinical studies to support the planned NDA submission for the treatment of VVC in the second half of 2020, and a net increase in other clinical expenses of $0.8 million, offset in part by a $1.4 million decrease in expense associated with our DOVE Phase 2 study that was substantially completed by the end of 2018, and a decrease of $0.8 million in expense associated with the initiation and completion of a Phase 1 study evaluating the pharmacokinetics, safety, and tolerability of oral ibrexafungerp in healthy subjects in 2018. The $0.6 million increase in CMC for the year ended December 31, 2019, was primarily driven by increased costs associated with the development and manufacture of drug product for ongoing and planned clinical studies as well as the registration batches necessary for the planned NDA submission for the treatment of VVC. The $1.1 million increase in salary and personnel related costs is due to the increase in full time employees from the comparable prior period. The $1.7 million decrease in preclinical expenses was primarily driven by certain toxicology and other studies incurred in the comparable prior period.

Selling, General and Administrative. For the year ended December 31, 2019, selling, general and administrative expenses increased to $10.6 million from $8.7 million for the year ended December 31, 2018. The increase of $2.0 million, or 22.7%, was primarily driven by a $1.0 million increase in business development and commercial related costs, a $0.6 million increase in professional fees, a $0.4 million increase in salary and personnel related costs, and a net increase in other selling, general and administrative expenses of $0.2 million, offset in part by a $0.2 million charge for deferred offering costs recognized in 2018.

Loss on Extinguishment of Debt. For the year ended December 31, 2019, we recognized a $0.8 million loss on debt extinguishment associated with the repayment of the term loan with Solar in March 2019 and a $0.2 million loss on debt extinguishment upon the conversion of a portion of our convertible debt in April 2019. The $0.8 million and $0.2 million losses recognized during the year ended December 31, 2019 represent the difference between the reacquisition prices and the net carrying values of the Solar and convertible debt balances extinguished, respectively.

Amortization of Debt Issuance Costs and Discount. For year ended December 31, 2019, amortization of debt issuance costs and discount increased to $1.2 million from $0.4 million for the year ended December 31, 2018. The 2019 debt issuance costs and discount comprised an allocated portion of the advisory fee and other issuance costs associated with our convertible debt and the fair value of the bifurcated derivative liability. The 2018 debt issuance costs comprised issuance costs, customary closing and final fees, and the fair value of the warrants issued in conjunction with the previous loan agreement with Solar.

Interest Income. For the years ended December 31, 2019 and 2018, we recognized $0.8 million and $1.0 million, respectively, in interest income associated with the short-term investments. The decrease in interest income was primarily due to the decrease in interest rate returns earned on our short-term investments in comparison to the comparable period.

Interest Expense. For the years ended December 31, 2019 and 2018, we recognized $1.0 million and $1.6 million, respectively, in interest expense associated with our convertible debt and prior loan agreement with Solar. The decrease from the prior comparable period is primarily due to the interest expense recognized for the previous loan agreement with Solar.

Other Income. For the year ended December 31, 2019, we recognized $0.5 million in other income associated with certain research and development tax credits.

Warrant Liabilities Fair Value Adjustment. For the years ended December 31, 2019 and 2018, we recognized a $4.5 million loss and a $11.9 million gain, respectively, for the fair value adjustment for warrant liabilities. The $4.5 million loss incurred during the year ended December 31, 2019 was primarily due to the increase in our stock price during the period.

Derivative Liability Fair Value Adjustment. For the year ended December 31, 2019, we recognized a gain of $1.6 million in the fair value adjustment related to the derivative liability primarily due to the decrease in our stock price during the period.

Income Tax Benefit. For the year ended December 31, 2018, we recognized a $6.7 million income tax benefit associated with the sale of a portion of our NOLs. This sale was structured through the New Jersey Technology Business Tax Certificate Transfer (NOL) Program.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2019, we had cash and cash equivalents and short-term investments of approximately $48.4 million, compared to $44.2 million as of December 31, 2018. The increase in our cash and cash equivalents and short-term investments was primarily due to the funds raised in our December 2019 public offering of our common stock and warrants and through our ATM, the cash receipt of $6.7 million received in 2019 for the sale of a portion of our New Jersey NOLs, offset in part by the continued development costs associated with our lead product candidate, ibrexafungerp.

We have incurred net losses since our inception, including the year ended December 31, 2019. As of December 31, 2019, our accumulated deficit was $271.4 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, New Jersey Technology Business Tax Certificate Transfer (NOL) Program), strategic alliances and licensing or collaboration arrangements. We may offer shares of our common stock pursuant to our Form S-3 shelf registration statement filed with the SEC on August 31, 2018 and declared effective on September 14, 2018, including the related at-market-facility entered into on August 31, 2018 with Cantor. For the year ended December 31, 2019, we received net proceeds of $11.0 million under our at-the-market facility.

On March 7, 2019, we sold to Puissance $16 million aggregate principal amount of our convertible senior notes (Notes). The holders of the Notes may convert their 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 our common stock. On or after March 15, 2022, we have the right, at our election to redeem all or any portion of the Notes not previously converted given certain sale price conditions associated with our common stock. See Note 7 to our consolidated financial statements for the year ended December 31, 2019, included in this Annual Report for further details.

Cash Flows

The following table sets forth the significant sources and uses of cash for theyears ended December 31, 2019 and 2018 (dollars in thousands):

	Years Ended December 31,	
	2019	2018
Cash, cash equivalents, and restricted cash, January 1	$ 11,767	$ 11,469
Net cash used in operating activities	(38,119)	(28,323)
Net cash provided by (used in) investing activities	26,240	(803)
Net cash provided by financing activities	42,305	29,424
Net increase in cash, cash equivalents, and restricted cash	30,426	298
Cash, cash equivalents, and restricted cash, December 31	**$ 42,193**	**$ 11,767**

Operating Activities

The $9.8 million increase in net cash used in operating activities for the year ended December 31, 2019, as compared to the year ended December 31, 2018,was primarily due to increases in costs associated with ibrexafungerp development efforts. We expect that our research and development expenses will increase as we pursue our ibrexafungerp development efforts and we expect we will continue to incur selling, general and administrative expenses to support our operations.

Net cash used in operating activities of $38.1 million for the year ended December 31, 2019,primarily consisted of the $53.7 million net loss adjusted for non-cash charges that included the loss on change in fair value of the warrant liabilities of $4.5 million and stock-based compensation expense of $1.8 million, the gain on change in fair value of the derivative liability of $1.6 million, the loss on extinguishment of debt of $1.0 million, and the amortization of debt issuance costs and discount of $1.2 million, plus a net favorable change in operating assets and liabilities of $8.3 million. The net favorable change in operating assets and liabilities included an increase in accounts payable and accrued expenses of $5.2 million primarily due to the increase in accounts payable and a decrease in prepaid expenses, other assets, and deferred costs of $3.3 million. The $3.3 million decrease in prepaid expenses, other assets, and deferred costs is primarily due the cash receipt of $6.7 million received in 2019 for the sale of a portion of our NOLs through the New Jersey Technology Business Tax Certificate Transfer (NOL) Program.

Net cash used in operating activities of $28.3 million for the year ended December 31, 2018, primarily consisted of the $12.5 million net loss adjusted for non-cash charges that included the gain on change in fair value of the warrant liabilities of $11.9 million and stock-based compensation expense of $1.8 million, plus a net unfavorable change in operating assets and liabilities of $6.4 million. The net unfavorable change in operating assets and liabilities included a decrease in accounts payable and accrued expenses of $0.2 million and an increase in prepaid expenses, other assets, and deferred costs of $6.4 million. The $6.4 million increase in prepaid expenses, other assets, and deferred costs is primarily due to the recognition of a $6.7 million receivable recorded as of December 31, 2018, for the sale of a portion of our NOLs through the New Jersey Technology Business Tax Certificate Transfer (NOL) Program.

Investing Activities

Net cash provided by investing activities of $26.2 million for the year ended December 31, 2019,consisted primarily of purchases and maturities of short-term investments of $39.5 million and $65.7 million, respectively.

Net cash used in investing activities of $0.8 million for the year ended December 31, 2018, consisted primarily of purchases and maturities of short-term investments of $85.1 million and $84.9 million, respectively.

Financing Activities

Net cash provided by financing activities of $42.3 million for the year ended December 31, 2019,consisted primarily of gross proceeds from common stock of $46.3 million, primarily as a result of our December 2019 public offering of common stock and warrants in additional to the gross proceeds from common stock sold under our at-the-market facility, partially offset by related underwriting discounts and commissions and offering expenses totaling $2.9 million. Additionally, pursuant to the note purchase agreement, we issued and sold to Puissance $16.0 million aggregate principal amount of our Notes, resulting in $14.7 million in net proceeds after deducting an advisory fee and other issuance costs, and we used the net proceeds to pay the remaining outstanding Solar term loan in full. As part of the payment of the outstanding balance of the Solar term loan, we paid $0.8 million in debt extinguishment costs which comprised the remaining unamortized discount and issuance costs associated with the Solar term loan prior to repayment.

Net cash provided by financing activities of $29.4 million for the year ended December 31, 2018, consisted of gross proceeds from common stock and warrants issued of $31.7 million, primarily as a result of our March 2018 offering of common stock and warrants, partially offset by related underwriting discounts and commissions and offering expenses totaling $2.3 million.

Future Funding Requirements

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize ibrexafungerp. 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, product candidates. We anticipate that we will need substantial additional funding in connection with our continuing future operations.

Based upon our existing operating plan, we believe that our existing cash and cash equivalents and short-term investments, and the sale of a portion of our New Jersey NOLs, will enable us to fund our operating requirements past a potential PDUFA date in mid-2021 for the treatment of VVC when we expect the FDA to complete the review of the NDA and potentially approve ibrexafungerp for the treatment of VVC. We are currently evaluating our operating plan and assessing the potential cash utilization impact of our updated 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 expenditures necessary to complete the development of product candidates.

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

- 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, New Jersey Technology Business Tax Certificate Transfer (NOL) Program), strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities as we did in April 2015, June 2016, March 2018, March 2019, and December 2019, 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 previous loan agreement with Solar or the convertible senior notes we sold in March 2019, 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.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Critical Accounting Policies and Significant 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 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 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, 2019, 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 and Deferred 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* (Topic 606), which became effective in the current period (we have elected to use the modified retrospective approach for contracts that are not completed contracts and there was no cumulative adjustment recognized in the current period) 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 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.

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, 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. 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.

We classify 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 we view such activities as being central to our 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, we defer and recognize revenue over the estimated period of our 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 our business operations, and (iii) the contractual terms of the arrangement.

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 progess 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,	
	2019	2018
Research and development, net	$ 604	$ 519
Selling, general and administrative	1,224	1,297
Total	$ 1,828	$ 1,816

On December 31, 2019, the aggregate intrinsic value of outstanding options to purchase shares of our common stock was $0.1 million, based upon the $0.91 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 do not have sufficient history to estimate the volatility of our common stock price. We estimate expected volatility based on a weighted average using reported data for selected reasonably similar publicly traded companies for which the historical information is available, our own history, and other valuation techniques. For the purpose of identifying peer companies, we consider characteristics such as industry, length of trading history, similar vesting terms and in-the-money option status. We plan to continue to use the guideline peer group volatility information until the historical volatility of our common stock is relevant to measure expected volatility for future option grants;

- 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, as our common stock has a limited trading history. 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, 2019 and 2018 are set forth below:

Employee Stock Options	Years Ended December 31,	
	2019	2018
Weighted average risk-free interest rate	2.47 %	2.64 %
Weighted average expected term (in years)	6.03	6.02
Weighted average expected volatility	66.47 %	52.31 %

Non-Employee Director Stock Options	Years Ended December 31,	
	2019	2018
Weighted average risk-free interest rate	2.11 %	2.44 %
Weighted average expected term (in years)	5.54	5.28
Weighted average expected volatility	65.36 %	58.65 %

Warrant Liabilities

We account for the outstanding warrants associated with the June 2016 public offering, March 2018 public offering, and December 2019 public offering 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.

Convertible Debt and Derivative Liability

For the Notes, we account for the bifurcated embedded conversion option, inclusive of the interest make-whole provision and make-whole fundamental change provision, as a long-term derivative liability in our consolidated balance sheet. The derivative liability is 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 liability at inception and on subsequent valuation dates. This model incorporates transaction details such as stock price, contractual terms, dividend yield, risk-free rate, historical volatility, credit rating, market credit spread, and estimated yield.

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 Stockholders 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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2020, expressed an unqualified opinion on the Company's internal control over financial reporting.

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 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. 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.

/s/ Deloitte & Touche LLP

Parsippany, New Jersey
March 11, 2020

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, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 41,920	$ 11,439
Short-term investments	6,494	32,718
Prepaid expenses and other current assets	3,988	7,251
Restricted cash	—	55
Total current assets	52,402	51,463
Other assets	812	812
Deferred offering costs	70	106
Restricted cash	273	273
Property and equipment, net	405	516
Operating lease right-of-use asset (Note 8)	3,191	—
Total assets	**$ 57,153**	**$ 53,170**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,177	$ 3,653
Accrued expenses	3,801	2,103
Deferred revenue, current portion	—	121
Operating lease liability, current portion (Note 8)	36	—
Total current liabilities	11,014	5,877
Warrant liabilities	18,396	986
Loan payable expected to be refinanced (Note 7)	—	15,082
Convertible debt and derivative liability (Note 7)	11,522	—
Operating lease liability (Note 8)	3,326	—
Total liabilities	44,258	21,945
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, authorized 5,000,000 shares as of December 31, 2019 and December 31, 2018; 0 shares issued and outstanding as of December 31, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value, 250,000,000 shares authorized as of December 31, 2019, and 125,000,000 shares authorized as of December 31, 2018; 97,413,721 and 47,971,989 shares issued and outstanding as of December 31, 2019, and December 31, 2018, respectively	97	48
Additional paid-in capital	284,226	248,895
Accumulated deficit	(271,428)	(217,718)
Total stockholders' equity	12,895	31,225
Total liabilities and stockholders' equity	**$ 57,153**	**$ 53,170**

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,	
	2019	**2018**
Revenue	$ 121	$ 257
Operating expenses:		
Research and development	38,394	21,560
Selling, general and administrative	10,648	8,680
Total operating expenses	49,042	30,240
Loss from operations	(48,921)	(29,983)
Other expense (income):		
Loss on extinguishment of debt	1,045	—
Amortization of debt issuance costs and discount	1,171	428
Interest income	(805)	(967)
Interest expense	986	1,626
Other income	(538)	—
Warrant liabilities fair value adjustment	4,497	(11,866)
Derivative liability fair value adjustment	(1,567)	—
Total other expense (income):	4,789	(10,779)
Loss before taxes	(53,710)	(19,204)
Income tax benefit	—	6,736
Net loss	$ (53,710)	$ (12,468)
Net loss per share – basic and diluted	$ (0.96)	$ (0.28)
Weighted average common shares outstanding – basic and diluted	56,081,384	43,883,995

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, 2017	28,971,651	$ 29	$ 226,631	$ (205,250)	$ 21,410
Net loss	—	—	—	(12,468)	(12,468)
Stock-based compensation expense	—	—	1,816	—	1,816
Common stock issued through employee stock purchase plan	31,361	—	39	—	39
Common stock issued, net of expenses	18,959,675	19	20,418	—	20,437
Common stock issued for vested restricted stock units	9,302	—	(9)	—	(9)
Balances as of December 31, 2018	47,971,989	$ 48	$ 248,895	$ (217,718)	$ 31,225
Net loss	—	—	—	(53,710)	(53,710)
Stock-based compensation expense	—	—	1,828	—	1,828
Common stock issued through employee stock purchase plan	36,847	—	37	—	37
Common stock issued, net of expenses	47,736,920	47	30,483	—	30,530
Common stock issued for April 2019 conversion of Notes	1,626,000	2	2,982	—	2,984
Common stock issued for exercise of stock options	22,500	—	12	—	12
Common stock issued for vested restricted stock units	19,465	—	(11)	—	(11)
Balances as of December 31, 2019	97,413,721	$ 97	$ 284,226	$ (271,428)	$ 12,895

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

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

	Years Ended December 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (53,710)	$ (12,468)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	111	53
Stock-based compensation expense	1,828	1,816
Accretion of investment discount	(16)	(111)
Amortization of debt issuance costs and discount	1,171	428
Change in fair value of warrant liabilities	4,497	(11,866)
Deferred offering write-off	—	230
Change in fair value of derivative liability	(1,567)	—
Noncash operating lease expense for right-of-use asset	174	—
Loss on extinguishment of debt	1,045	—
Changes in operating assets and liabilities:		
Prepaid expenses, other assets, and deferred costs	3,254	(6,367)
Accounts payable and accrued expenses	5,215	219
Deferred revenue	(121)	(257)
Net cash used in operating activities	(38,119)	(28,323)
Cash flows from investing activities:		
Maturities of investments	65,740	84,874
Purchases of property and equipment	—	(565)
Purchase of investments	(39,500)	(85,112)
Net cash provided by (used in) investing activities	26,240	(803)
Cash flows from financing activities:		
Proceeds from common stock issued	46,337	31,657
Payments of offering costs and underwriting discounts and commissions	(2,855)	(2,272)
Proceeds from employee stock purchase plan issuances	49	39
Proceeds from senior convertible notes	16,000	—
Payments of senior convertible notes issuance costs	(1,253)	—
Payment of loan payable expected to be refinanced	(15,973)	—
Net cash provided by financing activities	42,305	29,424
Net increase in cash, cash equivalents, and restricted cash	30,426	298
Cash, cash equivalents, and restricted cash at beginning of period	11,767	11,469
Cash, cash equivalents, and restricted cash at end of period	$ 42,193	$ 11,767
Supplemental cash flow information:		
Cash paid for interest	$ 850	$ 1,618
Cash received for interest	$ 898	$ 986
Noncash financing and investing activities:		
Operating lease liabilities arising from obtaining right-of-use assets	$ 3,365	—
Deferred offering costs reclassified to additional paid-in capital	$ 36	$ 84
Common stock issued for settlement of senior convertible notes	$ 2,984	—

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, pioneering innovative medicines to overcome and prevent difficult-to-treat and drug-resistant infections. The Company is developing its lead product candidate, ibrexafungerp, as the first representative of a novel oral and intravenous triterpenoid antifungal family for the treatment of several fungal infections, including serious and life-threatening invasive fungal infections.

The Company has incurred significant losses and negative cash flows from operations since its initial public offering in May 2014 and expects to continue to incur losses and negative cash flows for the foreseeable future. As a result, the Company had an accumulated deficit of $271.4 million at December 31, 2019 and limited capital resources to fund ongoing operations. These capital resources were primarily comprised of cash and cash equivalents of $41.9 million and short-term investments of $6.5 million at December 31, 2019. While the Company believes its capital resources are sufficient to fund the Company's on-going operations for a period of a least 12 months subsequent to the issuance of the accompanying consolidated financial statements, the Company's liquidity could be materially affected over this period by, among other things: (1) its ability to raise additional capital through equity offerings, debt financings, or other non-dilutive third-party funding; (2) costs associated with new or existing strategic alliances, or licensing and collaboration arrangements; (3) negative regulatory events or unanticipated costs related to its development of ibrexafungerp; or (4) any other unanticipated material negative events or costs. Should one or more of these negative events or costs materially affect its liquidity, the Company's available capital resources may not be sufficient for it to continue to meet its obligations as they become due over the next 12 months. If the Company is unable to meet its obligations when they become due, the Company may have to delay expenditures, reduce the scope of its research and development programs, or make significant changes to its operating plan. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

Shelf Registration Filing

On August 31, 2018, the Company filed a shelf registration statement on Form S-3 (File No. 333-227167) with the SEC, which was declared effective on September 14, 2018 (the "Shelf Registration"). The Shelf Registration contained three prospectuses:

- a base prospectus which covers the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $175.0 million of the Company's common stock, preferred stock, debt securities and warrants, including common stock or preferred stock issuable upon conversion of debt securities, common stock issuable upon conversion of preferred stock, or common stock, preferred stock or debt securities issuable upon the exercise of warrants;
- a prospectus covering the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $25.0 million of the Company's common stock that may be issued and sold under a Controlled Equity Offering Sales Agreement℠ (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor"). Pursuant to the Sales Agreement, the Company may sell from time to time, at its option, up to an aggregate of $25.0 million of the Company's common stock, through Cantor, as sales agent. Pursuant to the Sales Agreement, sales of the common stock, if any, will be made under the Company's effective Shelf Registration; and
- a warrant prospectus covering the offering, issuance, and sale of the Company's common stock issuable upon the exercise of warrants, consisting of (i) warrants to purchase 4,218,750 shares of the Company's common stock at an exercise price of $3.00 per share originally issued by the Company on June 24, 2016, (ii) warrants to purchase 13,198,075 shares of the Company's common stock at an exercise price of $1.85 per share originally issued by the Company on March 8, 2018, and (iii) warrants to purchase 7,988,175 shares of the Company's common stock at an exercise price of $2.00 per share originally issued by the Company on March 8, 2018. The warrants to purchase 13,198,075 shares of the Company's common stock expired on March 14, 2019. Upon full exercise for cash of the warrants outstanding on December 31, 2019, the holders of the warrants would pay the Company an aggregate of approximately $28.6 million. See Note 9 for further details.

The common stock that may be offered, issued and sold by the Company under the Sales Agreement is included in the $175.0 million of securities that may be offered, issued and sold by the Company under the base prospectus. Upon termination of the Sales Agreement with Cantor, any portion of the $25.0 million included in the Sales Agreement that is not

sold pursuant to the Sales Agreement will be available for sale in other offerings pursuant to the base prospectus and a corresponding prospectus supplement. As of December 31, 2019, approximately $127.5 million of securities registered under the base prospectus are available to be offered, issued and sold by the Company.

December 2019 Public Offering

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 38,888,889 shares of the Company's common stock and warrants to purchase up to an aggregate of 38,888,889 shares of the Company's common stock at a public offering price of $0.90 per share and accompanying warrant. Net proceeds from the December 2019 Public Offering were approximately $32.5 million, after deducting the underwriting discount and estimated offering expenses. In addition, the Company granted to the underwriters an option to purchase up to 5,833,333 additional shares of common stock and/or warrants to purchase up to an aggregate of an additional 5,833,333 shares of common stock, in each case at the public offering price, less underwriting discounts and commissions. The underwriters exercised their option to purchase 5,833,333 warrants in December 2019. The option to purchase up to 5,833,333 additional shares of common stock was not exercised by the underwriters and the option expired in January 2020. See Note 9 for further details.

March 2018 Public Offering

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 17,751,500 shares of the Company's common stock and warrants to purchase up to 21,301,800 shares of the Company's common stock at a public offering price of $1.69 per share. Net proceeds from the March 2018 Public Offering were approximately $27.9 million, after deducting the underwriting discount and estimated offering expenses. See Note 9 for further details.

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 include: 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, and short-term investments. 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.

Revenue recognized from a non-refundable upfront payment from R-Pharm, CJSC ("R-Pharm"), a collaboration partner, accounted for 100% of the Company's revenue for the years ended December 31, 2019 and 2018. No other parties contributed to the Company's revenue in 2019 and 2018.

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 $42.2 million and $11.8 million as of December 31, 2019 and 2018, respectively. See Note 8 for further details on the nature of the restricted cash.

Short-Term Investments

The Company's held-to-maturity investments in U.S. government securities, commercial paper, and its overnight repurchase agreement 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.

Warrant Liabilities

The Company accounts for the outstanding warrants associated with the June 2016 public offering, March 2018 Public Offering, and the December 2019 Public Offering 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. See Note 9 for further details.

Convertible Debt and Derivative Liability

In connection with the Company's issuance of its 6.0% Convertible Senior Notes due 2025 (the "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 Accounting Standards Codification ("ASC") 815, *Derivatives and Hedging* ("Topic 815"). The convertible debt and the derivative liability associated with the Notes are 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).

Revenue Recognition and Deferred 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* ("Topic 606"), 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.

The Company's August 2013 development, license, and supply agreement with R-Pharm, CJSC ("R-Pharm"), combined with the supplemental arrangement in November 2014 (the "R-Pharm Agreement"), is a collaborative arrangement pursuant to Topic 808. The Company received a non-refundable upfront payment of $1.5 million from R-Pharm in August 2013 which is being recognized over the estimated relationship period of 70 months for the combined performance obligation that includes the license of intellectual property and the participation on a joint steering committee. The Company recognized revenue from this upfront payment of $0.1 million and $0.3 million for the years ended December 31, 2019 and 2018, respectively. The Company is entitled to receive other payments under the R-Pharm Agreement including development and sales-based milestones and royalties; however, the variable consideration was fully constrained as of December 31, 2019.

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 year ended December 31, 2019, 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, 2019. 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 and forthe year ended December 31, 2019, there was no revenue recognized by the Company associated with this agreement given the variable consideration was fully constrained as of December 31, 2019.

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 which comprised issuance costs and an advisory fee. 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. Debt issuance costs allocated to the derivative liability were included in other expense as a component of the fair value adjustment for the year ended December 31, 2019. The Company's previous term loan with Solar Capital Ltd. ("Solar"), which was paid in full in March 2019 (see Note 7), 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 term loan. The resulting debt discount was being amortized over the term of the term loan using the straight-line method, which approximated 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.

Certain modifications made to an outstanding incentive stock option award at any time after the initial grant dates which are considered to be “material modifications”, as defined within the Internal Revenue Code, may result in the affected award being recharacterized as a non-statutory stock option. The effects of any recharacterization modification for purposes of income tax accounting are recognized on a prospective basis.

Stock-Based Compensation

The Company measures and recognizes compensation expense for all stock-based payment awards made to employees, officers, and directors 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-employee directors 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.

Basic and Diluted Net Loss per Share of Common Stock

The Company calculates net loss per common share in accordance withASC 260, *Earnings Per Share* ("Topic 260”). 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.

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,	
	2019	2018
Warrants to purchase Series C-1 Preferred	—	14,033
Warrants to purchase common stock associated with Solar loan agreement	122,435	122,435
Warrants to purchase common stock associated with June 2016 public offering	4,218,750	4,218,750
Warrants to purchase common stock associated with March 2018 Public Offering - Series 1	—	13,198,075
Warrants to purchase common stock associated with March 2018 Public Offering - Series 2	7,988,175	7,988,175
Outstanding stock options	5,261,860	4,052,913
Outstanding restricted stock units	966,394	111,891
Common stock associated with 6% convertible senior notes	11,382,000	—
Warrants to purchase common stock associated with December 2019 Public Offering	44,722,222	—
Option to purchase common stock associated with December 2019 Public Offering	5,833,333	—
Total	80,495,169	29,706,272

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, 2019 and 2018. 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 R-Pharm outside of the United States. All of the Company's revenue was generated from a non-refundable upfront payment received under a licensing and collaboration arrangement with a partner located in Russia. 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 Adopted Accounting Pronouncements

The Company adopted the FASB’s ASU No. 2016-02, *Leases*, or ASU 2016-02, on January 1, 2019, utilizing the modified retrospective basis. ASU 2016-02 requires lessees to recognize a right-of-use asset and lease liability, initially

measured at the present value of future lease payments, on the balance sheet and expands disclosure requirements regarding leasing arrangements. The Company elected the practical expedients under ASC 842-10-65-1(f) and ASC 842-10-15-37 that allowed the Company to forego the requirement to reassess the lease classification of its existing office lease and to combine the lease and nonlease components associated with its office lease as a single lease component. The consideration in the office lease that is 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 office 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 adoption of this accounting standard did not materially impact the Company's results of operations, other than the recognition of the operating lease right-of-use asset and lease liability. See Note 8 for further details.

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*, or 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)*, which revised the effective dates for ASU No. 2016-13. ASU No. 2019-10 is effective for smaller reporting companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2022, with early adoption permitted. The Company is currently evaluating the impact ASU 2016-13 will have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13,*Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, or ASU 2018-13. ASU 2018-13 removes, modifies and adds certain disclosure requirements in Topic 820, Fair Value Measurement. ASU 2018-13 eliminates certain disclosures related to transfers and the valuations process, modifies disclosures for investments that are valued based on net asset value, clarifies the measurement uncertainty disclosure, and requires additional disclosures for Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the impact ASU 2018-13 will have on its consolidated financial statements.

3. Short-term Investments

The following table summarizes the held-to-maturity securities held at December 31, 2019 and 2018 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
As of December 31, 2019				
U.S. government securities	$ 1,996	$ 15	$ (14)	$ 1,997
Commercial paper	998	—	—	998
Overnight repurchase agreement	3,500	—	—	3,500
Total short-term investments	$ 6,494	$ 15	$ (14)	$ 6,495

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
As of December 31, 2018				
U.S. government securities	$ 14,946	$ 14	$ (15)	$ 14,945
Commercial paper	8,772	—	—	8,772
Overnight repurchase agreement	9,000	—	—	9,000
Total short-term investments	$ 32,718	$ 14	$ (15)	$ 32,717

As of December 31, 2019, the Company has $6.5 million of held-to-maturity investments with contractual maturities less than one year. The gross unrealized gains and losses for the Company's commercial paper and overnight repurchase agreement are not significant. The Company carries short-term investments at amortized cost. The fair value of the short-term investments is determined based on "Level 1" inputs, which consist of quoted prices in active markets for identical assets.

4. Prepaid Expenses and Other Current Assets

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

	December 31,	
	2019	2018
Prepaid research and development services	$ 3,043	$ 245
Prepaid insurance	252	200
Other prepaid expenses	19	20
NOL sale receivable (see Note 10)	—	6,732
Other current assets	674	54
Total prepaid expenses and other current assets	$ 3,988	$ 7,251

5. Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31,	
	2019	2018
Furniture and fixtures	$ 406	$ 406
Computer equipment	73	73
Other	98	98
	577	577
Less: accumulated depreciation and amortization	(172)	(61)
Total property and equipment, net	$ 405	$ 516

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2019	2018
Accrued research and development expenses	$ 1,296	$ 587
Accrued employee bonus compensation	1,798	1,197
Other accrued expenses	707	319
Total accrued expenses	$ 3,801	$ 2,103

7. Borrowings

On September 30, 2016, the Company entered into a loan agreement with Solar, in its capacity as administrative and collateral agent and as lender. Pursuant to the loan agreement, Solar was providing the Company with a 48-month secured term loan in the amount of $15.0 million. The term loan bore interest at a floating rate equal to the LIBOR rate in effect plus 8.49%. The Solar term loan was paid in full in 2019.

On March 7, 2019, the Company entered into a Senior Convertible Note Purchase Agreement (the "Note Purchase Agreement") with Puissance Life Science Opportunities Fund VI ("Puissance"). Pursuant to the Note Purchase Agreement, on March 7, 2019, the Company issued and sold to Puissance $16.0 million aggregate principal amount of its Notes, resulting in $14.7 million in net proceeds after deducting $1.3 million for an advisory fee and other issuance costs. The Company used the net proceeds to pay the remaining outstanding Solar term loan in full and recorded a loss on debt extinguishment of $0.8 million during the year ended December 31, 2019. The loss on debt extinguishment of $0.8 million for the year ended December 31, 2019, was recognized as the difference between the reacquisition price of the outstanding Solar debt of $15.9 million and the $15.1 million net carrying value of the Solar debt obligation prior to repayment. In accordance with ASC 470-10-45-14(a), the Company reclassified the short-term portion of the Solar term loan on the balance sheet as of December 31, 2018 to long-term given the Company had the intent and ability to refinance the short-term obligation on a long-term basis.

In April 2019, Puissance converted $2.0 million of the Notes for 1,626,000 shares of common stock. Upon conversion of the $2.0 million of the Notes, the Company recognized a $0.2 million extinguishment loss which represents the difference between the total net carrying amount of the convertible debt and derivative liability of $2.8 million and the fair value of the consideration issued of $3.0 million.

As of December 31, 2019, the Company's $11.5 million in convertible debt and derivative liability consists of the convertible debt balance of $8.3 million presented net of the unamortized debt issuance costs allocated to the convertible debt of $0.5 million and the bifurcated embedded conversion option derivative liability of $3.2 million. In connection with the

Company's issuance of its 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. Debt issuance costs of $0.6 million initially allocated to the derivative liability were written off upon issuance of the Notes and were recognized in the loss on the fair value adjustment for the derivative liability for year ended December 31, 2019. For the year ended December 31, 2019, the Company recognized in other expense (income) on the consolidated statements of operations, a gain of $1.6 million on the fair value adjustment for the derivative liability and $1.1 million in amortization of debt issuance costs and discount related to the Notes.

The Company estimated the fair value of the convertible debt and derivative liability using a binomial lattice valuation model and Level 3 inputs. At December 31, 2019, the fair value of the senior convertible notes is $11.7 million.

The 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 Notes being issued to one financially sophisticated investor. The 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 Notes will mature on March 15, 2025, unless earlier converted, redeemed or repurchased. The Notes constitute general, senior unsecured obligations of the Company.

The holder of the Notes may convert their 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 739.0983 shares of common stock per $1,000 principal amount of Notes, which is equivalent to an initial conversion price of approximately $1.35, and is subject to adjustment in certain events described in the 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 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 Notes, including those delivered in connection with an interest make-whole payment, will not exceed a cap of 813 shares of common stock per $1,000 principal amount of the Notes.

On or after March 15, 2022, the Company has the right, at its election, to redeem all or any portion of the 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 Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. If a "fundamental change" (as defined in the Note Purchase Agreement) occurs, then, subject to certain exceptions, the Company must offer to repurchase the Notes for cash at a repurchase price of 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the repurchase date.

8. 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 840 (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 must furnish 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.

On January 1, 2019, a right-of-use asset and a corresponding operating lease liability of $3.4 million was recognized for the Lease. 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. In determining the operating lease liability at January 1, 2019, the Company utilized its incremental borrowing rate. The incremental borrowing rate 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 unaudited condensed consolidated financial statements for the Lease (dollars in thousands):

	Year Ended December 31, 2019
Operating lease cost	$ 664
Variable lease cost	41
Total operating lease expense	$ 705
Cash paid for amounts included in the measurement of operating lease liability	$ 497

	December 31, 2019
Remaining Lease term (years)	9.59
Discount rate	15 %

Rent expense was approximately $0.5 million for the year ended December 31, 2018. Future minimum lease payments for all operating leases as of December 31, 2019 and 2018 are as follows (in thousands):

	December 31, 2019
2020	$ 507
2021	517
2022	527
2023	715
2024	730
Thereafter	3,533
Total	$ 6,529

	December 31, 2018
2019	$ 498
2020	508
2021	518
2022	529
2023	716
Thereafter	4,203
Total	$ 6,972

The presentation of the operating lease liability and right-of-use asset as of December 31, 2019 and January 1, 2019 are as follows (in thousands):

	December 31, 2019	January 1, 2019
Present value of future minimum lease payments	$ 3,362	$ 3,368
Operating lease liability, current portion	$ 36	$ 23
Operating lease liability, long-term portion	3,326	3,345
Total operating lease liability	$ 3,362	$ 3,368
Difference between future minimum lease payments and discounted cash flows	$ 3,167	$ 3,604
Operating lease right-of-use asset	$ 3,191	$ 3,365

License Arrangements with Potential Future Expenditures

As of December 31, 2019, 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 is eligible to receive milestone payments from the Company that could total $19.0 million upon occurrence of specific events, including initiation of a Phase 3 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. Except as described above, all other terms and provisions of the license agreement remain in full force and effect. 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. The milestone payment was recognized in the consolidated statement of operations in research and development expense for the year ended December 31, 2019 and is included in cash used in operating activities on the consolidated statement of cash flows.

Clinical Development Arrangement

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.

9. 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 250,000,000 shares as of December 31, 2019, and 125,000,000 as of December 31, 2018; 97,413,721 and 47,971,989 shares were issued and outstanding at December 31, 2019, and December 31, 2018, respectively. On June 18, 2019, the Company's stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the total number of authorized shares of common stock from 125,000,000 to 250,000,000.

Shares Reserved for Future Issuance

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

	December 31,	
	2019	2018
Outstanding stock options	5,261,860	4,052,913
Outstanding restricted stock units	966,394	111,891
Outstanding Series C-1 Preferred warrants	—	14,033
Warrants to purchase common stock associated with June 2016 public offering	4,218,750	4,218,750
Warrants to purchase common stock associated with March 2018 Public Offering - Series 1	—	13,198,075
Warrants to purchase common stock associated with March 2018 Public Offering - Series 2	7,988,175	7,988,175
Warrants to purchase common stock associated with December 2019 Public Offering	44,722,222	—
Option to purchase common stock associated with December 2019 Public Offering	5,833,333	—
Common stock associated with 6% convertible senior notes	11,382,000	—
Warrants to purchase common stock associated with Solar loan agreement	122,435	122,435
For possible future issuance under 2014 Plan (Note 11)	554,774	612,018
For possible future issuance under 2014 ESPP (Note 11)	74,231	81,667
For possible future issuance under 2015 Plan (Note 11)	315,500	5,000
Total common shares reserved for future issuance	81,439,674	30,404,957

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, 2019 and 2018.

Convertible Debt and Derivative Liability

In connection with the Company's issuance of its 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 consolidated balance sheet in accordance with ASC 815, *Derivatives and Hedging*. The convertible debt and derivative liability associated with the Notes are presented in total on the accompanying consolidated balance sheet as the convertible debt and derivative liability. 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 (income) expense. For the year ended December 31, 2019, the Company recorded a gain of $1.6 million due to the change in fair value of the derivative liability. In April 2019, Puissance converted $2.0 million of the Notes for 1,626,000 shares of common stock.

Warrants Associated with June 2016, March 2018, and December 2019 Public Offerings

On June 21, 2016, the Company completed the June 2016 Public Offering and sold 9,375,000 shares of its common stock and warrants to purchase up to 4,218,750 shares of the Company's common stock. Each purchaser received a warrant to purchase 0.45 of a share for each share purchased in the June 2016 Public Offering. There is not expected to be any trading market for the warrants. Each warrant was exercisable immediately upon issuance, will expire five years from the date of issuance, and has an exercise price of $3.00 per share.

On March 8, 2018, the Company completed the March 2018 Public Offering and sold 17,751,500 shares of its common stock and warrants to purchase up to 21,301,800 shares of the Company's common stock. Each purchaser received a warrant to purchase 0.75 of a share of common stock (the "Series 1 warrants") and 0.45 of a share of common stock (the "Series 2 warrants") for each share purchased in the March 2018 Public Offering. The Series 1 warrants to purchase in the aggregate up to 13,313,625 shares of common stock had a 53-week term and an exercise price of $1.85 per share, and the Series 2 warrants to purchase in the aggregate up to 7,988,175 shares of common stock have a five-year term and an exercise price of $2.00 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. During the year ended December 31, 2018, there were 115,550 of the Series 1 warrants exercised for total proceeds of $0.2 million and the Series 1 warrants expired on March 14, 2019.

On December 12, 2019, the Company completed the December 2019 Public Offering and sold 38,888,889 shares of the its common stock and warrants to purchase up to 38,888,889 shares of the Company's common stock. 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 $1.10 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. In addition, the Company granted to the underwriters an option to purchase up to 5,833,333 additional shares of common stock and/or warrants to purchase up to an aggregate of an additional 5,833,333 shares of common stock, in each case at the public offering price, less underwriting discounts and commissions. The underwriters exercised their option to purchase 5,833,333 warrants in December 2019. The option to purchase up to 5,833,333 additional shares of common stock was not exercised by the underwriters and the option expired in January 2020.

The 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. During the year ended December 31, 2019, the Company recorded a loss of $4.5 million due to the change in fair value of the warrant liability. Issuance costs of $1.0 million initially allocated to the December 2019 Public Offering warrant liability were written off upon settlement and were recognized in the loss on the fair value adjustment for the warrant liability for the year ended December 31, 2019. As of December 31, 2019, the fair value of the warrant liabilities was $18.4 million.

Warrant Associated with Solar Loan Agreement

Pursuant to a loan agreement, the Company issued to Solar a warrant to purchase an aggregate of up to 122,435 shares of the Company's common stock at an exercise price of $3.6754 per share. The warrant will expire five years from the date of the grant. The warrant was classified as equity and recorded at its relative fair value at issuance in the stockholders' equity section of the balance sheet.

10. Income Taxes

The Company's consolidated financial statements include a total tax benefit of zero and $6.7 million on loss before taxes of $53.7 million and $19.2 million for the years ended December 31, 2019 and 2018, respectively. 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):

	2019		2018	
	Amount	Percent of Pretax Income	Amount	Percent of Pretax Income
Income taxes from continuing operations at statutory rate	$ (11,279)	21.0%	$ (4,033)	21.0%
State income taxes	(3,778)	7.0%	(985)	5.1%
State effect of permanent items	285	(0.5)%	(585)	3.0%
Stock-based compensation	100	(0.2)%	94	(0.5)%
Deferred rate change	(905)	1.6%	438	(2.3)%
Warrants issuance	733	(1.4)%	(2,492)	13.0%
Other	883	(1.5)%	71	(0.3)%
NOL sale	—	—	(3,938)	20.5%
R&D credit adjustment	(2,760)	5.1%	—	—
Increase in valuation allowance	16,721	(31.1)%	4,694	(24.4)%
Total income tax benefit	$ —	—%	$ (6,736)	35.1%

The components of deferred tax assets and liabilities as of December 31, 2019 and 2018 are as follows (in thousands):

	December 31,	
	2019	2018
Noncurrent deferred tax assets (liabilities)		
Accrued expenses	$ 107	$ 132
Stock-based compensation	2,436	1,911
Lease liability	945	—
Other	(856)	(31)
Net operating loss carryforwards	58,073	44,730
Research and development credits	5,984	3,226
Total deferred tax assets	66,689	49,968
Valuation allowances	(66,689)	(49,968)
Net deferred tax assets	$ —	$ —

As of December 31, 2019 and 2018, the Company had available federal net operating loss ("NOL") carryforwards of approximately $242.4 million and $194.9 million, respectively, and state and net operating loss carryforwards of approximately $178.2 million and $150.8 million, respectively. Approximately $171.9 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, 2019 and 2018 of approximately $47.5 million and $23.0 million, respectively, are carried forward indefinitely and do not expire. The Company's state and net operating loss carryforwards began to expire in 2018. As of December 31, 2019, the Company had available federal research and development credit carryforwards of $5.3 million which begin to expire in 2022.

The Company was eligible to receive cash from the sale of its Net Operating Losses underthe New Jersey Technology Business Tax Certificate Transfer (NOL) Program. In January 2019, the Company received a cash receipt of approximately $6.7 million from the sale of its state NOLs and recognized an income tax benefit of $6.7 million for the year ended December 31, 2018 in the statement of operations.

On December 22, 2017, the President signed into law the "Tax Cuts and Jobs Act." The new 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, 2019 and 2018, 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, 2019 and 2018 (in thousands):

	December 31,	
	2019	2018
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.

11. 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) 1,122,731 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, 2019 and 2018, the Company automatically added 1,918,879 and 1,158,866 shares to the total number shares of common stock available for future issuance under the 2014 Plan, respectively. As of December 31, 2019, there were 554,774 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 5635(c)(4). The 2015 Plan had an initial share reserve covering 450,000 shares of common stock. On June 9, 2019, the Company's board of directors amended the 2015 Plan, and the initial share reserve for the 2015 Plan was increased from 450,000 to 900,000 shares of common stock. During the year ended December 31, 2019, there were 115,000 granted options of the Company's common stock under the 2015 Plan. As of December 31, 2019, there were 315,500 shares of common stock available for future issuance under the 2015 Plan. During the year ended December 31, 2018, there were no granted options of the Company's common stock under the 2015 Plan. As of December 31, 2018, there were 5,000 shares of common stock available for future issuance under the 2015 Plan.

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 2019 and 2018 was $0.75 and $0.90 per option, respectively. The aggregate fair value of options granted during 2019 and 2018 was $1.3 million and $1.1 million, respectively. The assumptions used to estimate fair value and the resulting grant date fair values are as follows:

	Employees		Non-employee Directors	
	Years Ended December 31,		Years Ended December 31,	
	2019	2018	2019	2018
Weighted average expected volatility	66.47%	52.31%	65.36%	58.65%
Weighted average risk-free interest rate	2.47%	2.64%	2.11%	2.44%
Weighted average expected term (in years)	6.03	6.02	5.54	5.28

The activity for the 2009 Plan, 2014 Plan and 2015 Plan for the years ended December 31, 2019 is summarized as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value ($000)
Outstanding — January 1, 2019	4,052,913	$ 4.37	7.23	$ —
Granted	1,701,500	1.24		
Exercised	(22,500)	0.54		
Forfeited/expired	(470,053)	7.96		
Outstanding — December 31, 2019	5,261,860	$ 3.06	7.62	$ 60
Exercisable — December 31, 2019	2,988,580	$ 4.17	6.83	$ 33
Vested or expected to vest —December 31, 2019	5,261,860	$ 3.06	7.62	$ 60

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, 2019, and the exercise price multiplied by the number of options).

The total fair value of shares vested during the years endedDecember 31, 2019 and 2018 was $1.5 million and $1.8 million, respectively.

As of December 31, 2019, there was approximately $1.8 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the plan. That cost is expected to be recognized over a weighted-average period of 2.1 years.

Restricted stock unit ("RSU") activity under the 2014 Plan and 2015 Plan for the years ended December 31, 2019, is summarized as follows:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Non-vested at December 31, 2018	111,891	$ 2.06
Granted	932,500	1.37
Vested	(29,673)	2.14
Forfeited	(48,324)	1.46
Non-vested at December 31, 2019	966,394	$ 1.42

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, 2019, there was approximately $1.1 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 3.0 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 47,794 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) 29,411 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, 2019 and 2018, the Company issued 36,847 and 31,361 shares of common stock under the 2014 ESPP, respectively. During the years ended December 31, 2019 and 2018, the number of shares of common stock available for issuance under the ESPP was automatically increased by 29,411 shares. As of December 31, 2019, there were 74,231 shares of common stock available for future issuance under the 2014 ESPP.

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 $1.8 million for the years ended December 31, 2019 and 2018. 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, 2019 and 2018, respectively. Cash received from options exercised was $12,000 and $0 for the years ended December 31, 2019 and 2018, respectively.

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

	Years Ended December 31,	
	2019	2018
Research and development	$ 604	$ 519
Selling, general and administrative	1,224	1,297
Total stock-based compensation expense	$ 1,828	$ 1,816

12. Fair Value Measurements

The carrying amounts of certain financial instruments, including cash and cash equivalents, 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, 2019 and 2018 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, 2019				
Cash	$ 23	$ 23	—	—
Restricted cash	273	273	—	—
Money market funds	41,897	41,897	—	—
Total assets	$ 42,193	$ 42,193	—	—
Warrant liabilities	$ 18,396	—	—	$ 18,396
Derivative liability	3,192	—	—	3,192
Total liabilities	$ 21,588	—	—	$ 21,588
December 31, 2018				
Cash	$ 213	$ 213	—	—
Restricted cash	328	328	—	—
Money market funds	11,226	11,226	—	—
Total assets	$ 11,767	$ 11,767	—	—
Warrant liabilities	$ 986	—	—	$ 986
Total liabilities	$ 986	—	—	$ 986

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 liability 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 liability 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 Company uses the binomial lattice valuation model to value the Level 3 derivative liability 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 yield.

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, 2019	$ 986
December 2019 Public Offering warrants	13,921
Loss adjustment to fair value	3,489
Balance – December 31, 2019	$ 18,396

	Derivative Liability
Balance – January 1, 2019	$ —
Bifurcated embedded conversion option associated with Notes	6,960
Gain adjustment to fair value	(2,112)
Adjustment for April 2019 conversion of Notes	(1,656)
Balance – December 31, 2019	$ 3,192

13. 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 $0.1 million for the years ended December 31, 2019 and 2018.

14. Subsequent Events

Pursuant to the terms of the 2014 Plan (see Note 11), on January 1, 2020, the Company automatically added 3,896,548 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 11), on January 1, 2020, the Company automatically added 29,411 shares to the total number shares of common stock available for future issuance under the 2014 ESPP.

In January 2020, the Company entered into an agreement with a third party to sell a portion of its unused New Jersey NOLs and research and development credits for approximately $3.1 million.

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, 2019, 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, 2019, 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, 2019.

This annual report includes an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2019, 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 over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of SCYNEXIS, Inc. and subsidiaries (the "Company") as of December 31, 2019, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2019, of the Company and our report dated March 11, 2020, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP

Parsippany, New Jersey
March 11, 2020

ITEM 9B. OTHER INFORMATION

None.

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 2019 fiscal year pursuant to Regulation 14A for our 2020 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, 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 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	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 and 3.2.
4.2**	Description of Common Stock.
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 Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Stock Option Exercise. (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).
10.3*	SCYNEXIS, Inc. 2009 Stock Option Plan, as amended, and Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Stock Option Exercise. (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).
10.4*	SCYNEXIS, Inc. 2014 Equity Incentive Plan, as amended, (Filed with the SEC as Annex A to our proxy statement on Schedule 14A, filed with the SEC on April 22, 2015, SEC File No. 001-36365, and incorporated by reference here).
10.5*	SCYNEXIS, Inc. 2014 Employee Stock Purchase Plan. (Filed with the SEC as Exhibit 99.4 to our Registration Statement on Form 8, filed with the SEC on May 16, 2014, SEC File No. 333-196007, and incorporated by reference here).
10.6*	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).
10.7#	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).

10.8#	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).
10.9*	SCYNEXIS, Inc. Amended and Restated 2015 Inducement Award Plan. (Filed with the SEC as Exhibit 10.1 to our Quarterly Report on Form 10-Q, filed with the SEC on August 7, 2019, SEC File No. 001-36365, and incorporated by reference here).
10.10*	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).
10.11*	Employment Agreement, effective November 1, 2015, between SCYNEXIS, Inc. and Eric Francois. (Filed with the SEC as Exhibit 99.1 to our current report on Form 8-K, filed with the SEC on November 2, 2015, SEC File No. 001-36365, and incorporated by reference here, and incorporated by reference here).
10.12*	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).
10.13*	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).
10.14	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).
10.15#	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).
10.16#	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).
10.17#	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, 2018, SEC file No. 001-36365, and incorporated by reference here).
10.18*	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).
10.19*	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).
10.20	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, 2018, SEC file No. 001-36365, and incorporated by reference here).
10.21	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, 2018, SEC file No. 001-36365, and incorporated by reference here).
10.22	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, 2018, SEC file No. 001-36365, and incorporated by reference here).
10.23	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, 2018, SEC file No. 001-36365, and incorporated by reference here).

10.24*	Non-Employee Director Compensation Arrangements (Filed with the SEC as Exhibit 10.36 to our Annual Report on Form 10-K, filed with the SEC on March 14, 2019, SEC File No. 001-36365, and incorporated by reference here).
10.25	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).
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

Portions of this exhibit have been omitted pursuant to a request for confidential treatment, which portions were omitted and filed separately with the Securities and Exchange Commission.
* 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/ Marco Taglietti, M.D.
Marco Taglietti, M.D.
Chief Executive Officer
(Principal Executive Officer)

Date: March 11, 2020

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appointsMarco Taglietti and Eric Francois, as his 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 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/ Marco Taglietti, M.D. Marco Taglietti, M.D.	Chief Executive Officer (Principal Executive Officer)	March 11, 2020
/s/ Eric Francois Eric Francois	Chief Financial Officer (Principal Financial and Accounting Officer)	March 11, 2020
/s/ Guy Macdonald Guy Macdonald	Director	March 11, 2020
/s/ David Hastings David Hastings	Director	March 11, 2020
/s/ Steven C. Gilman, Ph.D. Steven C. Gilman, Ph.D.	Director	March 11, 2020
/s/ Ann F. Hanham, Ph.D. Ann F. Hanham, Ph.D.	Director	March 11, 2020
/s/ Armando Anido Armando Anido	Director	March 11, 2020
/s/ Brian Philippe Tinmouth Brian Philippe Tinmouth	Director	March 11, 2020

Exhibit 4.2

SCYNEXIS, INC.
DESCRIPTION OF COMMON STOCK

SCYNEXIS, Inc. ("***we***," "***our***," "***us***," or the "***Company***,") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"): our common stock.

The following description of our common stock does not purport to be complete and is subject in all respects to applicable Delaware law and to the provisions of our amended and restated certificate of incorporation, and our amended and restated bylaws.

General

Our amended and restated certificate of incorporation provides for common stock and authorized shares of undesignated preferred stock, the rights, preferences and privileges of which may be designated from time to time by our board of directors. Our authorized capital stock consists of 255,000,000 shares, all with a par value of $0.001 per share, of which 250,000,000 shares are designated as common stock and 5,000,000 shares are designated as preferred stock.

Common Stock

Voting Rights. Each holder of our common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders, except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law. Cumulative voting for the election of directors is not provided for in our amended and restated certificate of incorporation, which means that the holders of a majority of our shares of common stock can elect all of the directors then standing for election.

Dividends and Distributions. Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of outstanding shares of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its sole discretion, determines to issue dividends and only then at the times and in the amounts that our board of directors may determine.

Liquidation Rights. Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time after payment of liquidation preferences, if any, on any outstanding shares of preferred stock and payment of other claims of creditors. The rights, preferences, and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of holders of shares of any series of preferred stock that we may designate and issue in the future.

Preemptive or Similar Rights. Our common stock is not entitled to preemptive rights and is not subject to conversion, redemption or sinking fund provisions.

Anti-Takeover Provisions

Certificate of Incorporation and Bylaws

Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the voting power of our shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation and amended and restated bylaws provide that all stockholder actions must be effected at a duly called meeting of stockholders and not by consent in writing. A special meeting of stockholders may be called only by a majority of our whole board of directors, the chair of our board of directors, or our chief executive officer.

Our amended and restated certificate of incorporation further provides that the affirmative vote of holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then outstanding shares of voting stock, voting as a single class, are required to amend certain provisions of our certificate of incorporation, including provisions relating to the size of the board, removal of directors, special meetings, actions by written consent and cumulative voting. The affirmative vote of holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting

power of all of the then outstanding shares of voting stock, voting as a single class, is required to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors.

The foregoing provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of our company by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change the control of our company.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of our company. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy rights. However, these provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in control of our company or our management. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon closing of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by (1) persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statement No. 333-227167 on Form S-3 and Registration Statement Nos. 333-196007, 333-201048, 333-202830, 333-204771, 333-209997, 333-216652, 333-223624, 333-230278, and 333-233084 on Form S-8 of our reports dated March 11, 2020, relating to the financial statements of SCYNEXIS, Inc. and the effectiveness of SCYNEXIS, Inc.'s internal control over financial reporting, appearing in this Annual Report on Form 10-K of SCYNEXIS, Inc., for the year ended December 31, 2019.

/s/ Deloitte & Touche LLP

Parsippany, New Jersey
March 11, 2020

Exhibit 31.1

CERTIFICATIONS

I, Marco Taglietti, certify that:

1. I have reviewed this Form 10-K of SCYNEXIS, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2020

/s/ Marco Taglietti, M.D.

Marco Taglietti, M.D.
Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Eric Francois, certify that:

1. I have reviewed this Form 10-K of SCYNEXIS, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2020

/s/ Eric Francois

Eric Francois
Chief Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Marco Taglietti, Chief Executive Officer of SCYNEXIS, Inc. (the "Company"), and Eric Francois, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2019, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of March 11, 2020.

/s/ Marco Taglietti, M.D.	/s/ Eric Francois
Marco Taglietti, M.D. Chief Executive Officer	Eric Francois Chief Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of SCYNEXIS, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.