

May 8, 2019



# **SCYNEXIS Reports First Quarter 2019 Financial Results and Provides Company Update**

**Continued advancement of VVC program, including completed favorable embryo-fetal safety profile, further supports a potential first NDA submission of oral ibrexafungerp in the second half of 2020**

**Positive clinical data from ongoing FURI and CARES studies reinforce the potential role of oral ibrexafungerp as a novel therapy to combat severe and difficult-to-treat fungal infections, including multidrug-resistant *Candida auris***

**Cash runway past an anticipated NDA submission for VVC in the second half of 2020**

JERSEY CITY, N.J., May 8, 2019 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company delivering innovative therapies for difficult-to-treat and often life-threatening infections, today reported financial results for the quarter ended March 31, 2019, and provided an update on recent clinical developments.

"We are encouraged by the positive interim results and patient cases from our ongoing studies evaluating oral ibrexafungerp in severe and difficult-to-treat fungal infections," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "We also continue to advance oral ibrexafungerp in our ongoing Phase 3 VANISH study in patients with VVC, with the goal of sharing top-line data in the first half of 2020. In parallel, with the positive results seen in our complete reproductive and developmental toxicology package, we are moving closer to a potential New Drug Application (NDA) submission for VVC in the second half of 2020."

Ibrexafungerp (formerly SCY-078), the first representative of a novel family of compounds referred to as triterpenoids, is being developed for oral and intravenous administration and is in clinical development for the treatment of several serious fungal infections, including vulvovaginal candidiasis (VVC), invasive candidiasis (IC), invasive aspergillosis (IA) and refractory invasive fungal infections. If approved, ibrexafungerp would be the only oral alternative to azoles for the treatment of VVC and prevention of recurrent VVC.

## **Ibrexafungerp Update**

- **Data presented at the 2019 American College of Obstetrics and Gynecology Annual Clinical and Scientific Meeting (ACOG) support a future NDA submission**

**of oral ibrexafungerp for the treatment of VVC and highlight potential differentiation versus VVC standard-of-care.**

- Pre-clinical studies, conducted as part of a full reproductive and developmental toxicity package, showed that ibrexafungerp did not cause reproductive harm to adult animals or developmental harm to offspring. These findings are extremely meaningful for women with VVC, often of child-bearing age, and can differentiate oral ibrexafungerp against fluconazole, which has a warning for potential risks of spontaneous abortion and congenital abnormalities in its prescribing information.
  - Additional data presented further support the utility of ibrexafungerp as a treatment for VVC, including clinical results from a prior Phase 2b dose-finding study of oral ibrexafungerp in patients with VVC and preclinical data demonstrating *in vitro* activity against fluconazole-resistant *Candida* spp.
  - All ACOG 2019 posters and presentations can be found on the [SCYNEXIS website](#).
- **SCYNEXIS is currently enrolling patients in the VANISH Phase 3 registration program evaluating the safety and efficacy of oral ibrexafungerp in patients with acute VVC and is on track to initiate a planned Phase 3 trial for the prevention of recurrent VVC (the CANDLE study) in the second quarter of 2019.**
  - **New data from six presentations at the 29<sup>th</sup> European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) shows favorable clinical activity in difficult-to-treat fungal infections, including *Candida auris*.**
    - An oral presentation showcased results from the first interim analysis of 20 patients with various *Candida* infections from the FURI study, an open-label trial of oral ibrexafungerp in patients with refractory fungal infections. Oral ibrexafungerp demonstrated a clinical benefit in 17 of the 20 patients, with 11 patients achieving a complete or partial response and six patients achieving a stable disease response. Enrollment in the study continues to progress in the U.S. and Europe.
    - A poster presentation highlighted clinical findings for two patients with *Candida auris* candidemia enrolled in the CARES study, who were successfully treated with oral ibrexafungerp. *Candida auris* is a pathogen defined by the Centers for Disease Control and Prevention (CDC) as "an emerging fungus that presents a serious global health threat."
    - Preliminary results from the FURI and CARES studies build toward a potential future NDA submission through the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD).
    - All ECCMID 2019 posters and presentations can be found on the [SCYNEXIS website](#).

### **First Quarter 2019 Financial Results**

Cash, cash equivalents and short-term investments totaled \$39.1 million as of March 31, 2019, with net working capital of \$35.4 million.

Research and development expenses increased to \$9.7 million for the quarter ended March 31, 2019, compared to \$5.3 million in the first quarter of 2018. The increase of \$4.4 million, or 82%, was primarily driven by a milestone payment made during the quarter upon initiation

of the Phase 3 VVC registration study, an increase of \$1.1 million in clinical development, and a net increase of \$0.5 million in other research and development expenses, offset in part by a decrease of \$0.5 million in chemistry, manufacturing, and controls (CMC) and a decrease of \$0.7 million in preclinical development expense.

Selling, general and administrative expenses in the first quarter of 2019 increased to \$2.2 million, compared with \$2.0 million in the first quarter of 2018.

Total other expense was \$11.0 million in the first quarter of 2019, compared to total other income of \$3.2 million in the first quarter of 2018. The increase in other expense is attributable to the non-cash losses recognized during the first quarter of 2019 of \$6.5 million and \$3.4 million associated with the fair value adjustments for warrant liabilities and derivative liability, respectively. Additionally, during the first quarter of 2019, we recognized a loss on extinguishment of debt of \$0.8 million.

Net loss for the first quarter of 2019 was \$22.9 million, or \$0.46 per share. This compares with a net loss for the first quarter of 2018 of \$4.0 million, or \$0.12 per share.

### **About Ibrexafungerp**

Ibrexafungerp [pronounced eye-BREX-ah-FUN-jerp] is an investigational antifungal agent and the first representative of a novel family of compounds referred to as "fungerp" (antifungal triterpenoids). This agent combines the well-established activity of glucan synthase inhibitors with the potential flexibility of having oral and intravenous formulations. Ibrexafungerp has demonstrated broad spectrum antifungal activity, *in vitro* and *in vivo*, against multidrug-resistant pathogens, including azole- and echinocandin-resistant strains. Ibrexafungerp is currently in development for the treatment of fungal infections caused primarily by *Candida* (including *C. auris*) and *Aspergillus* species, and is being evaluated in multiple clinical programs: the VANISH registration program for the treatment of VVC is enrolling, the Phase 3 trial for the prevention of recurrent VVC is being initiated in the second quarter of 2019, the SCYNERGIA Phase 2 trial for invasive aspergillosis (IA) and the FURI and CARES Phase 3 trials for the treatment of patients with refractory infections are ongoing. The FDA has granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the formulations of ibrexafungerp for the indications of invasive candidiasis (IC) (including candidemia), IA and VVC, and has granted Orphan Drug Designation for the IC and IA indications. Ibrexafungerp is formerly known as SCY-078.

### **About SCYNEXIS**

[SCYNEXIS](http://www.scynexis.com), Inc. (NASDAQ:SCYX) is a biotechnology company committed to positively impacting the lives of patients suffering from difficult-to-treat and often life-threatening infections by developing innovative therapies. The [SCYNEXIS team](#) has extensive experience in the life sciences industry, having discovered and developed more than 30 innovative medicines over a broad range of therapeutic areas. SCYNEXIS's lead product candidate, ibrexafungerp (formerly known as SCY-078), is a novel IV/oral antifungal agent in Phase 3 clinical and preclinical development for the treatment of multiple serious and life-threatening invasive fungal infections caused by *Candida*, *Aspergillus* and *Pneumocystis* species. For more information, visit [www.scynexis.com](http://www.scynexis.com).

### **Forward Looking Statement**

Statements contained in this press release regarding expected future events or results are "forward-looking statements" within the meaning of the Private Securities Litigation Reform

Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, but are not limited, to: risks inherent in SCYNEXIS's ability to successfully develop and obtain FDA approval for ibrexafungerp; the expected costs of studies and when they might begin or be concluded; whether the positive results from the FURI trial to date will continue to be achieved as the study continues; uncertainties about the regulatory standards for approval through LPAD; and SCYNEXIS's reliance on third parties to conduct SCYNEXIS's clinical studies. These and other risks are described more fully in SCYNEXIS's filings with the Securities and Exchange Commission, including without limitation, its most recent Annual Report on Form 10-K under the caption "Risk Factors" and other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. SCYNEXIS undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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

	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Revenue	\$ 64	\$ 64
Operating expenses:		
Research and development	9,684	5,326
Selling, general and administrative	2,241	1,971
Total operating expenses	11,925	7,297
Loss from operations	(11,861)	(7,233)
Other expense (income):		
Loss on extinguishment of debt	814	-
Amortization of debt issuance costs and discount	200	111
Interest income	(281)	(167)
Interest expense	367	379
Warrant liabilities fair value adjustment	6,522	(3,554)
Derivative liability fair value adjustment	3,425	-

Total other expense (income):	11,047	(3,231)
<b>Net loss</b>	<b>\$ (22,908)</b>	<b>\$ (4,002)</b>
Net loss per share – basic and diluted	\$ (0.46)	\$ (0.12)
Weighted average common shares outstanding – basic and diluted	49,317,575	33,579,025

**SCYNEXIS, INC.**  
**UNAUDITED CONDENSED BALANCE SHEETS**  
(in thousands, except share and per share data)

	<u>March 31, 2019</u>	<u>December 31, 2018</u>
Cash and cash equivalents	\$ 12,950	\$ 11,439
Short-term investments	26,110	32,718
Total current assets	40,073	51,463
Operating lease right-of-use asset	3,317	–
Total assets	45,067	53,170
Total current liabilities	4,638	5,877
Warrant liabilities	7,508	986
Loan payable expected to be refinanced	–	15,082
Convertible debt and derivative liability	18,296	–
Operating lease liability	3,295	–
Total liabilities	33,737	21,945
Total stockholders' equity	11,330	31,225
Total liabilities and stockholders' equity	\$ 45,067	\$ 53,170

View original content: <http://www.prnewswire.com/news-releases/scynexis-reports-first-quarter-2019-financial-results-and-provides-company-update-300846618.html>

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