

SCYNEXIS Reports Second Quarter 2018 Financial Results and Provides Company Update

Oral dose regimen of ibrexafungerp (formerly SCY-078) identified for Phase 3 VVC development; Phase 3 on track for initiation in the fourth quarter of 2018

Development of ibrexafungerp intravenous (IV) formulation delayed

Continued progress in our strategy to expand the use of oral ibrexafungerp in multiple indications

Adequate funds to support operations into 2020

JERSEY CITY, N.J., Aug. 9, 2018 /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 June 30, 2018, and provided an update on recent operational and clinical developments.

"With the positive results from our Phase 2b DOVE study in vulvovaginal candidiasis (VVC), we achieved a meaningful milestone in our efforts to make ibrexafungerp available to patients in need and to bring to market the first new antifungal class in nearly 20 years," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "While we continue to face challenges with the development of our IV formulation, we are pleased with the advancement and further de-risking of oral ibrexafungerp, which has the potential to address unmet medical needs in a variety of severe infections and improve the lives of patients."

Ibrexafungerp (formerly SCY-078) Update

- **600mg Oral Dose of Ibrexafungerp Identified for Phase 3 VVC Development; Phase 3 On Track for Initiation in the Fourth Quarter of 2018, with Potential NDA Filing in 2020.**
 - In July 2018, SCYNEXIS reported positive top-line data from the Phase 2b DOVE study evaluating several dose regimens of oral ibrexafungerp for the treatment of VVC, compared to fluconazole (FLU), the standard of care for VVC. The 600mg dose of ibrexafungerp was well-tolerated, with strong overall clinical and mycological activity and improved sustained effect compared to FLU.
 - Pending the End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA), we believe the 600mg dose of ibrexafungerp for one day (given as two doses of 300mg 12 hours apart) is the optimal dose regimen. We intend to use this dose in the VVC Phase 3 registration program, on track for initiation in the fourth quarter of 2018, and, pending successful completion of this trial, we anticipate filing an initial NDA for the treatment of VVC in 2020. Ibrexafungerp may represent the first new oral treatment for this indication in 25 years, and we believe it may provide significant benefits for the large number of patients not well-served by existing therapies.
- **Development Delay with 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. 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.
- **Continued Progress on Company's Strategy to Expand the Use of Ibrexafungerp in Indications Where**

the Oral Formulation is a Viable Treatment Option to Address Significant Unmet Needs.

- **Initiation of Phase 2 Combination Study Testing Oral Ibrexafungerp in Invasive Aspergillosis on Track for this Quarter.** Encouraged by the improved outcomes and survival rates seen in an animal model of pulmonary aspergillosis, we plan to start a study in patients with invasive aspergillosis (IA) in the third quarter of 2018. The study will assess the safety and efficacy of oral ibrexafungerp in combination with azole therapy, the standard of care for this indication.
- **Open-label FURI and CARES Studies Ongoing with Preliminary Data Review Planned for the Fourth Quarter of 2018.** These studies are designed to enroll patients with a wide range of *Candida* spp. infections with limited or no treatment options and are designed for potential expedited regulatory approval via the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD).
- **SCY-078 Granted "Ibrexafungerp" as Non-proprietary Name by WHO.** In assigning ibrexafungerp as the generic name of SCY-078, the World Health Organization (WHO) incorporated a novel stem (-fungerp), recognizing ibrexafungerp as the first member of a new triterpenoid drug class. With the last new antifungal class approved in 2001, ibrexafungerp has the potential to impact the rapidly rising resistance rates observed in many fungal species to today's standards of care.
- **Oral Ibrexafungerp Granted QIDP and Fast Track Designations for the Treatment of VVC and the Prevention of VVC Recurrence.** The Qualified Infectious Disease Product (QIDP) designation allows for priority review and an additional five years of market exclusivity in the U.S. The FDA's Fast Track Drug Development Program is designed to facilitate the development and expeditious review of drugs to treat serious conditions and fill unmet medical needs.
- **Presentations at Medical Meetings and Peer-reviewed Publications.** SCYNEXIS presented ibrexafungerp data at medical meetings and published data in a peer-reviewed journal. The data demonstrate the potent antifungal activity of ibrexafungerp against a broad range of fungal species, including echinocandin-resistant strains, as well as highlight numerous unique attributes, including lack of teratogenicity, synergistic activity with azoles and low risk of interactions with agents metabolized by CYP enzymes. Collectively, the data support the investigation of ibrexafungerp across a spectrum of antifungal indications, including VVC, invasive candidiasis (IC), IA, resistant fungal infections and prophylaxis indications.
 - In July 2018, at the 20th Congress of the International Society for Human and Animal Mycology, SCYNEXIS presented pre-clinical data demonstrating that ibrexafungerp has fungicidal activity against *C. auris*.
 - In June 2018, at the Teratology Society 58th Annual Meeting, SCYNEXIS presented pre-clinical data demonstrating that ibrexafungerp shows no impact on fertility or early embryo/fetal activity, potentially clinically relevant for women who are pregnant or may become pregnant.
 - In June 2018, at the 20th International Symposium on Infections in the Immunocompromised Host, SCYNEXIS presented pre-clinical data demonstrating that ibrexafungerp has activity alone, as well as synergistic activity with azole agents, against *Aspergillus* spp.
 - In June 2018, at the American Society for Microbiology Microbe 2018, SCYNEXIS presented data demonstrating that ibrexafungerp has potent *in vitro* activity against echinocandin-resistant *Candida*, as well as exhibits synergistic activity with isavuconazole against *Aspergillus* spp.
 - In June 2018, in *The Journal of Clinical Pharmacology*, SCYNEXIS published Phase 1 data demonstrating that ibrexafungerp has a low risk of interactions with drugs metabolized by CYP enzymes, potentially clinically relevant for patients with Type 2 diabetes.
 - In April 2018, at the 28th European Congress of Clinical Microbiology and Infectious Diseases, SCYNEXIS presented data demonstrating the *in vitro* activity of ibrexafungerp against *Aspergillus* spp., as well as the *in vivo* activity of ibrexafungerp against *Pneumocystis* pneumonia, supporting potential use for prophylaxis indications.

Second Quarter 2018 Financial Results

Cash, cash equivalents and short-term investments totaled \$55.2 million as of June 30, 2018, with net working capital of \$43.4 million. SCYNEXIS expects its cash, cash equivalents and short-term investments at June 30, 2018 will be sufficient to fund operations into 2020.

Research and development, net expenses increased to \$5.6 million in the second quarter of 2018, compared to \$4.4 million in the second quarter of 2017. The increase of \$1.2 million, or 26%, for the three months ended June 30, 2018, was primarily driven by an increase of \$0.8 million in pre-clinical development expense and a \$1.0 million increase in clinical development expense; offset by a decrease in regulatory expense of \$0.2 million and a decrease of \$0.4 million in consulting expense.

Selling, general and administrative expenses decreased to \$2.1 million in the second quarter of 2018, compared to \$2.4 million in the second quarter of 2017. The decrease of \$0.2 million, or 10%, for the three months ended June 30, 2018, was primarily driven by a decrease in business development related expenses and legal fees incurred during the three months ended June 30, 2018.

Total other expense decreased to \$3.1 million in the second quarter of 2018 due to a \$2.9 million non-cash loss recorded on the fair value adjustment of the warrant liabilities.

Net loss for the second quarter of 2018 was \$10.8 million, or \$0.23 per share. This compares with a net loss for the second quarter of 2017 of \$4.2 million, or \$0.16 per share.

About Ibrexafungerp (formerly SCY-078)

Ibrexafungerp [pronounced eye-BREX-ah-FUN-jerp] is an investigational antifungal agent and the first representative of a novel class of structurally-distinct glucan synthase inhibitors, triterpenoids. This agent combines the well-established activity of glucan synthase inhibitors with the potential flexibility of having oral and IV formulations. Ibrexafungerp is currently in development for the treatment of fungal infections caused primarily by *Candida* (including *C. auris*) and *Aspergillus* species. It has demonstrated broad spectrum antifungal activity, *in vitro* and *in vivo*, against multidrug-resistant pathogens, including azole- and echinocandin-resistant strains. The FDA has granted QIDP and Fast Track designations for the formulations of ibrexafungerp for the indications of IC (including candidemia), IA and VVC, and has granted Orphan Drug Designation for the IC and IA indications.

About SCYNEXIS

SCYNEXIS, Inc. ([NASDAQ:SCYX](https://www.nasdaq.com/markets/stocks/quotes/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, discovering and developing more than 30 innovative medicines over a broad range of therapeutic areas. SCYNEXIS's lead product candidate, ibrexafungerp (formerly SCY-078), is a novel oral/IV antifungal agent in Phase 2 clinical and pre-clinical development for the treatment of multiple serious and life-threatening invasive fungal infections caused by *Candida* and *Aspergillus* species. For more information, visit 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, including without limitation, statements regarding: expectations for the timing of initiation of, and dosing in, clinical trials; anticipated timing for filing an initial NDA in 2020; plans to start a study in IA in the third quarter of 2018; plans for review of FURI and CARES. 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; and SCYNEXIS's reliance on third parties to conduct SCYNEXIS's clinical studies and to manufacture product supplies. 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)

	Three Months Ended June 30,	
	2018	2017
Revenue	\$ 64	\$ 64
Operating expenses:		
Research and development, net	5,599	4,448
Selling, general and administrative	2,123	2,361
Total operating expenses	7,722	6,809
Loss from operations	(7,658)	(6,745)
Other expense (income):		
Amortization of debt discount	99	100
Interest income	(271)	(82)
Interest expense	397	360
Warrant liabilities fair value adjustment	2,874	(2,924)
Total other expense (income)	3,099	(2,546)
Net loss	\$ (10,757)	\$ (4,199)
Net loss per share - basic and diluted	\$ (0.23)	\$ (0.16)
Weighted average common shares outstanding - basic and diluted	46,843,524	25,813,675

SCYNEXIS, INC.
UNAUDITED CONDENSED BALANCE SHEETS
(in thousands)

	June 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 6,769	\$ 11,469
Short-term investments	48,425	32,424
Total current assets	56,507	44,960
Total assets	58,050	45,850
Loan payable, current portion	5,474	4,349
Warrant liability	3,220	—
Total current liabilities	13,154	10,144
Warrant liabilities	8,953	3,872
Loan payable, long term	9,390	10,303
Total liabilities	31,497	24,440
Total stockholders' equity	26,553	21,410
Total liabilities and stockholders' equity	\$ 58,050	\$ 45,850

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