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SCYNEXIS Reports Third Quarter 2018 Financial Results and Provides Company Update

JERSEY CITY, N.J., Nov. 13, 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 September 30, 2018, and provided an update on recent clinical and operational developments.

Key Messages:

- Women suffering from vaginal yeast infections (vulvovaginal candidiasis or VVC) have only one approved oral treatment option. With SCYNEXIS's U.S. Food and Drug Administration (FDA)-endorsed Phase 3 registration program for VVC on track to begin by year-end, and with a potential New Drug Application (NDA) filing planned for 2020, ibrexafungerp may become the much-needed oral alternative for the millions of women who are not well-served by fluconazole.
- Despite existing therapies, mortality associated with invasive aspergillosis remains as high as 50%. Based on positive pre-clinical data, an ibrexafungerp combination regimen has the potential to show superiority to the current standard of care. SCYNEXIS has initiated a Phase 2 study as a proof of concept in this indication.
- Patients with no therapeutic options for invasive fungal infections continue to enroll in SCYNEXIS's ibrexafungerp programs designed for such refractory infections, including infections caused by *Candida auris*, a multidrug-resistant pathogen that is the subject of recent warnings by the Centers for Disease Control and Prevention (CDC) and other health authorities.
- As of September 30, 2018, SCYNEXIS has \$49.5 million in cash and cash equivalents and short-term investments, adequate to fund activities into 2020.

"With our successful End-of-Phase 2 Meeting with the FDA, we continue to advance toward our goal of bringing ibrexafungerp to patients in need," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "Following FDA's agreement with our proposed overall design of the Phase 3 registration program for VVC, we anticipate that results showing superiority of ibrexafungerp over placebo would lead to filing an NDA in 2020 for the treatment of VVC, followed by a supplemental NDA in 2021 for the prevention of recurrent VVC."

Dr. Taglietti continued: "In parallel, we are advancing the development of ibrexafungerp for severe, invasive indications. We continue to enroll patients in our FURI study for the

treatment of refractory infections; we recently dosed the first patient in our CARES study for the treatment of high-mortality *Candida auris* infections and we initiated our Phase 2 combination study for the treatment of invasive aspergillosis. We remain committed to maximizing the clinical utility of ibrexafungerp, a first-in-class therapy that combines the broad-spectrum antifungal activity and safety profile of the echinocandin class with the oral convenience of the azole class. With a cash runway into 2020, we are well-funded to progress all ongoing programs."

Ibrexafungerp (formerly SCY-078) Update

- **VVC Phase 3 Registration Program on Track for Initiation by End of 2018, with Potential NDA Filing in 2020.**
 - In October 2018, SCYNEXIS announced the successful completion of an End-of-Phase 2 Meeting with the FDA for VVC. The FDA has agreed with the SCYNEXIS's proposed design of the Phase 3 registration program to support approval of oral ibrexafungerp for the treatment of VVC and the prevention of recurrent VVC. SCYNEXIS anticipates initiating the program by the end of 2018.
 - If approved, ibrexafungerp would provide a much-needed oral option for the millions of women who are currently not well-served by existing VVC therapies. Fluconazole, approved over 25 years ago, is the only oral treatment available and fails to adequately address several patient segments: fluconazole-failure patients, management of VVC during pregnancy, moderate-to-severe VVC, recurrent VVC and VVC caused by fluconazole-resistant *Candida* spp.

- **Continued Progress on SCYNEXIS's Strategy to Expand the Use of Ibrexafungerp in Severe Invasive Fungal Infections.**
 - In October 2018, SCYNEXIS dosed the first patient in the CARES study, a Phase 3, multi-center (U.S. and India), open-label, single-arm study evaluating the efficacy, safety and tolerability of oral ibrexafungerp for the treatment of *Candida auris* infections. *C. auris* is an emerging life-threatening and multidrug-resistant fungal pathogen, with a mortality rate of up to 60%.
 - The FURI study, evaluating oral ibrexafungerp for the treatment of fungal infections refractory or resistant to standard of care, is ongoing with a preliminary data review planned by the end of the year.
 - SCYNEXIS recently initiated a Phase 2 combination study of oral ibrexafungerp in invasive aspergillosis. An animal model of pulmonary aspergillosis showed improved outcomes and survival rates, supporting the potential superiority of ibrexafungerp in combination with azole therapy versus the standard of care.
 - Ibrexafungerp is well-positioned to address significant unmet needs in patients suffering from severe invasive fungal infections. It is a first-in-class therapy, with broad-spectrum activity (including against multidrug-resistant strains), fungicidal activity versus *Candida*, high tissue penetration and a favorable safety profile. These features, available in the convenience of an oral formulation, differentiate ibrexafungerp from available alternatives, and, if approved, would make it an attractive option for the treatment of severe invasive fungal infections.

- **Presentation at the 2018 ESCMID/ASM Conference on Drug Development.** In September 2018, SCYNEXIS presented a poster at the 2018 European Society of Clinical Microbiology and Infectious Diseases (ESCMID)/American Society for Microbiology (ASM) Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance. The poster, titled "Ibrexafungerp (formerly SCY-078) Displays Potent *In Vitro* Activity Against *C. Glabrata* Isolates with Mutations in *fks* Genes," describes the results of several pre-clinical studies designed to evaluate the *in vitro* activity of ibrexafungerp in *Candida glabrata* strains with *fks* mutations, which are often contributory in the development of echinocandin resistance. *C. glabrata* is the second-most common fungal species isolated from blood in the US and one of the most common fungal pathogens worldwide.

Third Quarter 2018 Financial Results

Cash, cash equivalents and short-term investments totaled \$49.5 million as of September 30, 2018, with net working capital of \$39.1 million.

Research and development expenses decreased to \$3.9 million in the third quarter of 2018, compared to \$4.5 million in the third quarter of 2017. The decrease of \$0.5 million, or 12%, for the three months ended September 30, 2018, was primarily driven by a decrease of \$0.8 million in preclinical development expense and a decrease of \$0.2 million in consulting expense and was offset in part by an increase of \$0.5 million in chemistry, manufacturing, and controls.

Selling, general and administrative expenses increased to \$2.4 million in the third quarter of 2018, compared with \$2.0 million in the third quarter of 2017. The increase of \$0.4 million, or 21%, for the three months ended September 30, 2018, was primarily driven by a \$0.2 million charge for deferred offering costs recognized during the three months ended September 30, 2018.

Total other income increased to \$6.7 million in the third quarter of 2018 due to a \$6.9 million non-cash gain recorded on the fair value adjustment of the warrant liabilities.

Net income for the third quarter of 2018 was \$0.4 million, or \$0.01 per share. This compares with a net loss for the third quarter of 2017 of \$8.4 million, or \$0.31 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 Qualified Infectious Disease Product (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) 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; timing of planned NDA filings and preliminary reviews of data, and the adequacy of resources to fund activities into 2020. 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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	Three Months Ended September 30,	
	2018	2017
Revenue	\$ 64	\$ 64
Operating expenses:		
Research and development, net	3,933	4,459
Selling, general and administrative	2,433	2,004
Total operating expenses	6,366	6,463
Loss from operations	(6,302)	(6,399)
Other (income) expense:		
Amortization of debt discount	103	100
Interest income	(260)	(109)
Interest expense	435	373
Warrant liabilities fair value adjustment	(6,931)	1,638
Total other (income) expense	(6,653)	2,002
Net income (loss)	351	(8,401)
Net income (loss) per share attributable to common stakeholders - basic		
Net income (loss) per share - basic	0.01	(0.31)
Net income (loss) per share attributable to common stockholders - diluted		
Net income (loss) per share - diluted	0.01	(0.31)
Weighted average common shares outstanding		
Basic	46,988,844	27,091,061
Diluted	47,025,503	27,091,061

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

	September 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 16,080	\$ 11,469
Short-term investments	33,408	32,424
Total current assets	50,235	44,960
Total assets	51,650	45,850
Loan payable, current portion	7,349	4,349
Warrant liability	174	—
Total current liabilities	11,086	10,144
Warrant liabilities	5,068	3,872
Loan payable, long term	7,617	10,303
Total liabilities	23,771	24,440
Total stockholders' equity	27,879	21,410
Total liabilities and stockholders' equity	\$ 51,650	\$ 45,850

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