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SCYNEXIS Reports Third Quarter 2019 Financial Results and Provides Company Update

Following positive Phase 3 VANISH-303 top-line data, oral ibrexafungerp VVC program passes critical milestone toward an NDA submission planned for the second half of 2020

Substantial commercial opportunity for oral ibrexafungerp in VVC as potential novel treatment of choice for the large number of women currently underserved by existing agents

Ongoing hospital program of oral ibrexafungerp as salvage treatment for patients with resistant or refractory severe fungal infections, including Candida auris, expanded to a broader range of indications potentially eligible for LPAD regulatory pathway

Second interim data review from the FURI study expected in the first quarter of 2020

Cash runway expected to fund operations past an anticipated NDA submission for VVC in the second half of 2020

JERSEY CITY, N.J., Nov. 12, 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 September 30, 2019, and provided an update on recent clinical developments. 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 first agent approved for the treatment of VVC and prevention of recurrent VVC and the only oral alternative to azoles.

"We are thrilled with the positive top-line results from the VANISH-303 study and are increasingly confident in an anticipated NDA submission for the treatment of VVC next year as we work to bring ibrexafungerp, potentially the first new class of antifungals approved in over 20 years, to patients in need," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "We believe the VVC market is quite large and underserved by existing agents, with only one FDA-approved oral drug in the market, which has lacked

innovation since the introduction of fluconazole in the 1990s. We're confident in the commercial potential of ibrexafungerp given its differentiated attributes as a new oral, non-azole antifungal and the eagerness of women with VVC and their treating physicians to try new therapies."

Dr. Taglietti continued: "We are also enthusiastically advancing our hospital-based development programs of ibrexafungerp as a novel treatment to fight invasive, increasingly drug-resistant and often life-threatening fungal infections, such as *Candida auris*. As part of this effort, we recently announced the expansion of our FURI protocol to a broader range of refractory, serious fungal infections that are potentially eligible for a limited-population FDA approval under the LPAD regulatory pathway. Given the robust evidence collected to date across all of our programs, we believe ibrexafungerp can have the same positive impact fluconazole had when it was first introduced nearly 30 years ago, leveraging ibrexafungerp's versatility and strong attributes in many different treatment settings – from women's health with VVC to deadly, hospital-based infections."

Ibrexafungerp Update

- **Positive top-line data reported for the first of two studies in the VANISH Phase 3 program evaluating the safety and efficacy of oral ibrexafungerp (300mg BID for one day) versus placebo as a treatment for women with VVC**
  - SCYNEXIS recently announced positive results from theVANISH-303 study, a Phase 3, randomized, double-blind, placebo-controlled, study that enrolled 376 patients at 28 U.S. centers. These results were reported earlier than originally anticipated due to rapid enrollment in the study.
  - The primary endpoint required for registration is clinical cure, defined as complete resolution (score of 0) of all signs and symptoms (S&S) at the Day-10 test-of-cure (TOC) visit. 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). Clinical improvement (S&S 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). 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.
  - 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 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.
  - A second global Phase 3 study (VANISH-306), with identical design, is being conducted in the U.S. and Europe. Enrollment continues to progress rapidly, and the Company anticipates top-line data early in the second quarter of 2020. The

combined results from the VANISH-303 and VANISH-306 pivotal studies are expected to provide the safety and efficacy data to support a New Drug Application (NDA) for ibrexafungerp for the treatment of VVC, with submission to the U.S. Food and Drug Administration (FDA) planned in the second half of 2020.

- **Ongoing enrollment in Phase 3 CANDLE study evaluating the safety and efficacy of oral ibrexafungerp versus placebo for the prevention of recurrent VVC**
  - The CANDLE study is a global Phase 3, randomized, double-blind, placebo-controlled trial designed to evaluate the safety and efficacy of oral ibrexafungerp (300mg BID for one day, given once per month for a total of six treatment days) compared to placebo in female patients with recurrent VVC (defined as three or more episodes of VVC in the past 12 months, including the episode at screening). The study is being conducted at approximately 50 sites and is expected to enroll approximately 320 patients. Pending a positive outcome, the Company anticipates filing a supplemental NDA for the prevention of recurrent VVC with the FDA in 2021.

- **Continued advancement of oral ibrexafungerp for hospital-based, invasive fungal infections with two Phase 3 studies (FURI in refractory infections and CARES in *Candida auris* infections) and one Phase 2 study in invasive aspergillosis (SCYNERGIA)**
  - The protocol for the FURI study, investigating the safety and efficacy of oral ibrexafungerp as a salvage treatment for patients with resistant or refractory severe fungal infections, was expanded to include a broader range of infections. 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. Additionally, the maximum allowed duration of treatment with ibrexafungerp has been extended from 90 days to up to 180 days, as needed, for chronic conditions. Ibrexafungerp will also be available as a combination therapy with standard of care for selected patients.
  - Continued and expanded patient enrollment is expected to support future NDA submissions and potential approval through the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD). The Company anticipates reporting a second interim data review from the FURI study by an independent data review committee in the first quarter of 2020.
  - Enrollment is ongoing for the CARES and SCYNERGIA studies.

- **Data presented at 3rd International Society of Infectious Diseases in Obstetrics and Gynecology (ISIDOG), IDWeek 2019 and the 9th Congress on Trends in Medical Mycology (TIMM-9) further highlighting the scientific and clinical evidence of ibrexafungerp's activity against multiple fungal pathogens**
  - Post-hoc data from the Phase 2b DOVE study presented at ISIDOG 2019 highlighted ibrexafungerp's improved trend in signs and symptoms versus

fluconazole on a per patient basis.
    - Data presented at IDWeek 2019 highlighted a large body of evidence demonstrating the activity and efficacy of ibrexafungerp against *Candida auris*, both *in vivo* and *in vitro.*
    - In an oral presentation at TIMM-9, studies demonstrating ibrexafungerp's broad spectrum of activity against *Candida*, *Aspergillus*, and *Pneumocystis* were presented, along with evidence of its activity against resistant organisms and ibrexafungerp's potential utility for the treatment of hospital-based resistant and refractory fungal infections. Additional posters presented provided *in vitro, in vivo* and clinical evidence of ibrexafungerp's broad utility against multiple fungal pathogens.

Corporate Highlight

- **SCYNEXIS received notification from the State of New Jersey of its available unused Net Operating Losses (NOLs) and R&D credits and expects to receive approximately $3.3 million in cash by the end of 2019.**
    - The New Jersey Economic Development Authority's (NJEDA) Technology Business Tax Certificate Transfer (NOL) Program allows eligible companies to sell their New Jersey NOLs and research and development tax credits up to a maximum lifetime benefit of $15 million per company. This may be the second non-dilutive NOL-related cash injection through the NJEDA for SCYNEXIS. In January 2019, SCYNEXIS announced the receipt of approximately $6.7 million of net cash proceeds through the sale of unused New Jersey NOLs.

Third Quarter 2019 Financial Results

Cash, cash equivalents and short-term investments totaled $28.1 million as of September 30, 2019, with net working capital of $20.9 million. Based upon its existing operating plan, SCYNEXIS believes its existing cash, cash equivalents, short-term investments, and the sale of a portion of its New Jersey NOLs, may enable SCYNEXIS to fund operating requirements past an anticipated NDA submission for acute VVC in the second half of 2020.

Research and development expenses increased to $9.3 million for the quarter ended September 30, 2019, compared to $3.9 million in the third quarter of 2018. The increase of $5.3 million, or 136%, was primarily driven by an increase of $4.1 million in clinical development costs, an increase of $0.7 million in chemistry, manufacturing, and controls (CMC) costs, and a net increase in other research and development costs of $0.5 million.

Selling, general and administrative expenses in the third quarter of 2019 increased to $2.5 million, compared with $2.4 million in the third quarter of 2018.

Total other income decreased to $3.8 million in the third quarter of 2019, compared to $6.7 million in the third quarter of 2018. The decrease in other income is attributable to a $6.9 million non-cash gain recorded on the fair value adjustment of the warrant liabilities during the third quarter of 2018.

Net loss for the third quarter of 2019 was $7.9 million. This compares with net income for the third quarter of 2018 of $0.4 million.

About Ibrexafungerp
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 intravenous (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 invasive candidiasis (IC) (including candidemia), invasive aspergillosis (IA) and VVC (including prevention of recurrent VVC) and has granted Orphan Drug Designation for the IC and IA indications. Ibrexafungerp is formerly known as SCY-078.

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, 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.

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 clinical studies to date will continue to be achieved as the studies continues; uncertainties about the regulatory standards for approval; 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 CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Three Months Ended September 30,	
	2019	**2018**
Revenue	$ –	$ 64
Operating expenses:		
Research and development	9,276	3,933
Selling, general and administrative	2,480	2,433
Total operating expenses	11,756	6,366
Loss from operations	(11,756)	(6,302)
Other (income) expense:		
Amortization of debt issuance costs and discount	306	103
Interest income	(170)	(260)
Interest expense	203	435
Warrant liabilities fair value adjustment	(1,830)	(6,931)
Derivative liability fair value adjustment	(2,324)	–
Total other income:	(3,815)	(6,653)
Net (loss) income	$ (7,941)	$ 351
Net (loss) income per share attributable to common stockholders - basic		
Net (loss) income per share - basic	$ (0.14)	$ 0.01
Net (loss) income per share attributable to common stockholders - diluted		
Net (loss) income per share - diluted	$ (0.15)	$ 0.01
Weighted average common shares outstanding		
Basic	55,697,391	46,988,844
Diluted	67,079,391	47,025,503

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

	September 30, 2019	**December 31, 2018**
Cash and cash equivalents	$ 11,619	$ 11,439
Short-term investments	16,487	32,718
Total current assets	28,960	51,463

Operating lease right-of-use asset		3,238		–
Total assets		33,816		53,170
Total current liabilities		8,092		5,877
Warrant liabilities		3,629		986
Loan payable expected to be refinanced		–		15,082
Convertible debt and derivative liability		12,574		–
Operating lease liability		3,378		–
Total liabilities		27,673		21,945
Total stockholders' equity		6,143		31,225
Total liabilities and stockholders' equity	$	33,816	$	53,170

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