August 7, 2019

SCYNEXIS Reports Second Quarter 2019 Financial Results and Provides Company Update

Significant progress made in Phase 3 VANISH program evaluating oral ibrexafungerp for the treatment of VVC, with NDA submission anticipated in the second half of 2020

Enrollment in the global study (VANISH 306) is progressing as planned with top-line data anticipated in the second quarter of 2020, while enrollment in the U.S. study (VANISH 303) is exceeding expectations with top-line data now anticipated in the first quarter of 2020

Special Protocol Assessment agreement received from the FDA for Phase 3 CANDLE study evaluating oral ibrexafungerp for the prevention of recurrent VVC; on-track to start enrollment this quarter

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

JERSEY CITY, N.J., Aug. 7, 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 June 30, 2019, and provided an update on recent clinical developments.

"We are pleased with the rapid enrollment observed in our Phase 3 VANISH program for vulvovaginal candidiasis (VVC), which underscores the significant unmet need in this patient population," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "We look forward to sharing top-line data from the U.S. study in the first quarter of 2020, and from the global study in the second quarter of 2020. We are making great progress toward our goal of a planned New Drug Application (NDA) submission for VVC in the second half of 2020."

Dr. Taglietti continued, "We are committed to maximizing the full value of ibrexafungerp in multiple settings. As we approach important milestones for our VVC registration program, we are also excited by the promising data supporting the potential role of oral ibrexafungerp as a treatment for a broad range of life-threatening, hospital-based, fungal infections, including *Candida auris* and other multidrug-resistant pathogens for which few existing treatment options are available."

Ibrexafungerp (formerly SCY-078), the first representative of a novel family of antifungal

compounds referred to as triterpenoids, is being developed for oral and intravenous (IV) administration and is in clinical development for the treatment of both serious outpatient fungal infections, including VVC, and hospital-based life-threatening fungal infections, including invasive candidiasis (IC), invasive aspergillosis (IA) and refractory invasive fungal infections. If approved, ibrexafungerp could potentially address significant unmet medical needs as the only oral non-azole antifungal therapy.

Ibrexafungerp Update

- **Significant progress made in Phase 3 VANISH program evaluating the safety and efficacy of oral ibrexafungerp (300mg BID for one day) versus placebo for the treatment of VVC**
  - The VANISH Phase 3 program is comprised of two Phase 3, randomized, double-blind, placebo-controlled, multicenter studies:
    - The VANISH 303 study is being conducted in U.S. centers and is expected to enroll approximately 350 patients; enrollment in the study is exceeding expectations and SCYNEXIS anticipates top-line data in the first quarter of 2020. More information about this study can be found at: https://clinicaltrials.gov/ct2/show/NCT03734991
    - The global VANISH 306 study is being conducted in U.S. and European centers and is expected to enroll approximately 350 patients; enrollment is progressing as planned, and the Company anticipates top-line data in the second quarter of 2020. More information about this study can be found at: https://clinicaltrials.gov/ct2/show/NCT03987620
  - All NDA preparatory activities remain on track to support a planned NDA submission in the second half of 2020.
- **Phase 3 CANDLE study evaluating the safety and efficacy of oral ibrexafungerp versus placebo for the prevention of recurrent VVC is on track to start enrollment this quarter following the Special Protocol Assessment (SPA) agreement received from the U.S. Food and Drug Administration (FDA) in July 2019**
  - The Company recently announced an agreement with the FDA under a SPA, on the design, trial population, endpoints and statistical analysis of the CANDLE study, a pivotal Phase 3 clinical trial of oral ibrexafungerp for the prevention of recurrent VVC. 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.
  - The CANDLE study is a global Phase 3, randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety 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. Enrollment is expected to commence this quarter with an expected supplemental NDA submission in 2021.
  - More information about the CANDLE study can be found at: https://clinicaltrials.gov/ct2/show/NCT04029116
- **An open-label sub-study within CANDLE will evaluate the efficacy of oral**

ibrexafungerp in fluconazole-failure VVC patients
    - All patients in the CANDLE study will initially receive three doses of oral fluconazole to treat their acute episode of VVC present at screening before progressing to the prevention phase of the study.
    - Patients who fail to sufficiently respond to fluconazole treatment for their acute episode will be included in the sub-study, in which they will be offered one day of oral ibrexafungerp treatment (300mg BID) for their unresolved acute episode.
    - More information about the sub-study within the CANDLE study can be found at: https://clinicaltrials.gov/ct2/show/NCT04029116
- **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)**
    - Enrollment is ongoing in the Company's refractory invasive fungal infection (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). 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*. More information about these studies can be found at:
      https://clinicaltrials.gov/ct2/show/NCT03059992
      https://clinicaltrials.gov/ct2/show/NCT03363841
    - Enrollment continues in the Phase 2 SCYNERGIA study, a randomized, double-blind clinical trial assessing the safety and efficacy of oral ibrexafungerp in combination with voriconazole, compared to voriconazole alone. More information about this study can be found at:
      https://clinicaltrials.gov/ct2/show/NCT03672292
- **Data presented at the American Society for Microbiology (ASM) Microbe 2019 Meeting demonstrates broad potential utility of ibrexafungerp for the treatment and prevention of multiple severe fungal infections**
    - A total of nine presentations revealed data further demonstrating the potential of ibrexafungerp as a treatment for invasive fungal infections (visit scynexis.com/science to view the presentations). The data presented highlighted the potent activity of ibrexafungerp against difficult-to-treat and/or multidrug-resistant pathogens, including *Candida auris*, *Candida glabrata*, and *Pneumocystis* pneumonia. The activity of ibrexafungerp was tested against many *Candida* strains resistant to echinocandins, the current standard of care for these infections, and potent activity of ibrexafungerp was observed.
    - *In vivo* chronic toxicology studies further support the safety profile of ibrexafungerp, allowing for patients suffering from invasive fungal infections to use oral ibrexafungerp for an extended period of time and enabling its potential development as a prophylactic agent and as a treatment for chronic fungal infections.

Corporate Highlight

- **Management Team strengthened with appointment of Dr. Nkechi Azie as Vice President of Clinical Development.**

- SCYNEXIS announced the appointment of Nkechi Azie, MD, MBA, FIDSA, as Vice President of Clinical Development. Dr. Azie will lead clinical development activities and strengthen medical affairs efforts in anticipation of ibrexafungerp's potential approval and commercial launch. She joins SCYNEXIS with over 25 years of experience in drug development and medical affairs, having worked in therapeutic areas including infectious disease, women's health and immunology.

Second Quarter 2019 Financial Results

Cash, cash equivalents and short-term investments totaled $35.2 million as of June 30, 2019, with net working capital of $28.9 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 net operating losses (NOLs), will be sufficient to fund operations beyond the planned NDA submission for acute VVC in the second half of 2020.

Research and development expenses increased to $8.5 million for the quarter ended June 30, 2019, compared to $5.6 million in the second quarter of 2018. The increase of $2.9 million, or 51%, was primarily driven by an increase of $3.2 million in clinical development costs, an increase of $0.4 million in chemistry, manufacturing, and controls (CMC) costs, a net increase in other research and development costs of $0.6 million, offset in part by a decrease of $1.3 million in preclinical development expense.

Selling, general and administrative expenses in the second quarter of 2019 increased to $2.8 million, compared with $2.1 million in the second quarter of 2018. The increase of $0.7 million, or 31%, was primarily driven by a $0.4 million increase in business development costs.

Total other income increased to $2.8 million in the second quarter of 2019, compared to a $3.1 million loss in the second quarter of 2018. The increase in other income is attributable to the non-cash gains recognized during the second quarter of 2019 of $2.0 million and $1.3 million associated with the fair value adjustments for warrant liabilities and derivative liability, respectively.

Net loss for the second quarter of 2019 was $8.4 million, or $0.16 per share. This compares with a net loss for the second quarter of 2018 of $10.8 million, or $0.23 per share.

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, 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* 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. 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)

	Three Months Ended June 30,	
	2019	**2018**

Revenue	$	57	$	64
Operating expenses:				
Research and development		8,474		5,599
Selling, general and administrative		2,779		2,123
Total operating expenses		11,253		7,722
Loss from operations		(11,196)		(7,658)
Other (income) expense:				
Loss on extinguishment of debt		231		–
Amortization of debt issuance costs and discount		373		99
Interest income		(233)		(271)
Interest expense		209		397
Warrant liabilities fair value adjustment		(2,049)		2,874
Derivative liability fair value adjustment		(1,324)		–
Total other (income) expense:		(2,793)		3,099
Net loss	$	(8,403)	$	(10,757)
Net loss per share – basic and diluted	$	(0.16)	$	(0.23)
Weighted average common shares outstanding – basic and diluted		53,277,660		46,843,524

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

		June 30, 2019		December 31, 2018
Cash and cash equivalents	$	19,150	$	11,439
Short-term investments		16,080		32,718
Total current assets		36,143		51,463
Operating lease right-of-use asset		3,284		–
Total assets		41,074		53,170
Total current liabilities		7,248		5,877
Warrant liabilities		5,459		986
Loan payable expected to be refinanced		–		15,082
Convertible debt and derivative liability		14,592		–
Operating lease liability		3,401		–
Total liabilities		30,672		21,945
Total stockholders' equity		10,402		31,225
Total liabilities and stockholders' equity	$	41,074	$	53,170

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