November 6, 2020

SCYNEXIS Reports Third Quarter 2020 Financial Results and Provides Company Update

- *In October, SCYNEXIS submitted a New Drug Application (NDA) for ibrexafungerp for the treatment of vulvovaginal candidiasis (VVC) with expected approval in mid-2021.*
- *SCYNEXIS estimates that there are over 15 million antifungal prescriptions written each year for the treatment of VVC.*
- *Enrollment is ongoing in the Phase 3 CANDLE study of oral ibrexafungerp for the prevention of recurrent vaginal yeast infections; top-line results and a second NDA submission anticipated in the second half of 2021.*
- *Enrollment continues in clinical studies of oral ibrexafungerp for the treatment of serious and life-threatening fungal infections, including those caused by drug-resistant* Candida auris*, recognized by the CDC as an urgent threat to public health.*

JERSEY CITY, N.J., Nov. 06, 2020 (GLOBE NEWSWIRE) -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company pioneering innovative medicines to potentially overcome and prevent difficult-to-treat and drug-resistant infections, today reported financial results for the third quarter ended on September 30, 2020 and provided an update on recent clinical and corporate developments.

“We submitted our NDA for ibrexafungerp for the treatment of vaginal yeast infections ahead of schedule and, with approval anticipated in mid-2021, we continue to progress towards our transition into a fully integrated commercial-stage antifungal company with an initial focus on women’s health,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “In parallel, we are also advancing clinical trials evaluating ibrexafungerp’s potential to treat invasive fungal infections in the hospital setting, with additional data read-outs expected in 2021.”

Ibrexafungerp Update

- **SCYNEXIS recently announced the submission of its NDA to the U.S. Food and Drug Administration (FDA) for oral ibrexafungerp for the treatment of VVC, also known as vaginal yeast infection**. The submission occurred in October and SCYNEXIS expects to receive FDA feedback on the acceptability of this submission in December. As a qualified infectious disease product (QIDP), ibrexafungerp is expected to receive a six-month priority review following NDA acceptance with a PDUFA date anticipated in mid-2021.

- **Enrollment is ongoing in the Phase 3 CANDLE study, investigating the efficacy and safety of oral ibrexafungerp for the prevention of recurrent VVC, for which there is no approved therapy in the U.S.** Pending successful completion of this trial, SCYNEXIS anticipates top-line results and the submission of a supplemental NDA for this indication in the second half of 2021.

- **Enrollment is ongoing in our refractory invasive fungal infections (rIFI) program, which comprises two open-label Phase 3 studies (FURI and CARES).** Similar to the two interim analyses of previously reported data, SCYNEXIS intends to analyze the outcomes from the next cohort of patients that have completed their treatment course in both FURI and CARES studies and announce these findings when available.

- **Enrollment is ongoing in the Phase 2 SCYNERGIA study for patients with invasive aspergillosis** evaluating oral ibrexafungerp in combination with voriconazole. Top-line data from this study are expected in the second half of 2021.

- **Pre-clinical activities are also ongoing towards the development of a liposomal intravenous formulation of ibrexafungerp.**

- **Data presentations.** In October 2020, SCYNEXIS presented ibrexafungerp data at two scientific conferences. The first was the Nurse Practitioners in Women's Health (NPWH) held virtually on October 15-17, where SCYNEXIS showcased *in vitro* activity of ibrexafungerp against fluconazole-susceptible and -resistant *Candida* species, as well as data from the Phase 3 VANISH-303 trial in VVC. The second October conference was IDWeek 2020 held virtually on October 21-25. At this conference SCYNEXIS presented an interim analysis from its ongoing Phase 3 FURI trial in refractory infections and pre-clinical data highlighting the potential for ibrexafungerp use in invasive fungal infections. In August 2020, SCYNEXIS presented its full data set from the Phase 3 VANISH-303 VVC trial at the Infectious Diseases Society for Obstetrics and Gynecology (IDSOG). Some of the posters presented are available here.

Corporate Developments

- On July 17, 2020, SCYNEXIS executed a 1-for-10 reverse split of its issued and outstanding common stock.

Third Quarter Financial Results

Cash and cash equivalents totaled $29.5 million as of September 30, 2020, compared to $48.4 million in cash, cash equivalents, and short-term investments at December 31, 2019.

Research and development expense for the three months ended September 30, 2020 decreased to $8.0 million from $9.3 million for the three months ended September 30, 2019. The decrease of $1.2 million, or 13%, for the three months ended September 30, 2020, was primarily driven by a decrease of $2.0 million in clinical development expense, and a decrease of $0.5 million in preclinical expense, offset in part by an increase in regulatory expense of $0.6 million, an increase of $0.3 million in chemistry, manufacturing, and controls

(CMC) expense, and a net increase in other research and development expense of $0.4 million.

Selling, general and administrative expenses for the quarter ended September 30, 2020 increased to $3.5 million from $2.5 million for the quarter ended September 30, 2019. The increase of $1.0 million, or 40%, for the three months ended September 30, 2020 was primarily driven by a $0.8 million increase in professional fees and commercial related expenses recognized during the three months ended September 30, 2020.

Total other income was $12.4 million for the quarter ended September 30, 2020, compared to total other income of $3.8 million for the quarter ended September 30, 2019. During the quarter ended September 30, 2020 and 2019, SCYNEXIS recognized non-cash gains of $7.8 million and $1.8 million, respectively, on the fair value adjustment of the warrant liabilities and during the quarter ended September 30, 2020 and 2019, recognized non-cash gains of $5.3 million and $2.3 million on the fair value adjustment of the derivative liabilities, respectively.

Net income for the quarter ended September 30, 2020 was $0.9 million, or $0.09 per basic and ($0.28) per diluted share, compared to a net loss of $7.9 million, or ($1.43) per basic and ($1.45) per diluted share for the quarter ended September 30, 2019.

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, 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 pioneering innovative medicines to potentially help millions of patients worldwide overcome and prevent difficult-to-treat infections that are becoming increasingly drug-resistant. Our lead candidate, ibrexafungerp (formerly known as SCY-078), is a broad-spectrum, IV/oral antifungal agent representing a novel therapeutic class, in late stage development for multiple indications, ranging from vaginal yeast infections to life-threatening fungal infections in hospitalized patients. The SCYNEXIS team has deep expertise in anti-infective drug development and marketing, which can be leveraged to advance ibrexafungerp from clinical development to commercialization. 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 but not limited to statements regarding timelines for review and approval of ibrexafungerp for the treatment of VVC, as well as expectations for reporting clinical data. 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; unexpected delays may occur in the timing of acceptance by the FDA of the NDA submission; the expected costs of studies and when they might begin or be concluded; SCYNEXIS's need for additional capital resources; 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 and Quarterly Report on Form 10-Q, in each case under the caption "Risk Factors," and in 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.

CONTACT:
Investor Relations
Irina Koffler
LifeSci Advisors
Tel: (646) 970-4681
ikoffler@lifesciadvisors.com

Media Relations
Gloria Gasaatura
LifeSci Communications
Tel: (646) 970-4688
ggasaatura@lifescicomms.com

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

	Three Months Ended September 30,	
	2020	**2019**
Revenue	$ –	$ –
Operating expenses:		
Research and development	8,030	9,276
Selling, general and administrative	3,481	2,480
Total operating expenses	11,511	11,756
Loss from operations:	(11,511)	(11,756)
Other (income) expense:		

Amortization of debt issuance costs and discount	311	306
Interest income	(5)	(170)
Interest expense	330	203
Other expense	20	–
Warrant liabilities fair value adjustment	(7,786)	(1,830)
Derivative liabilities fair value adjustment	(5,290)	(2,324)
Total other income	(12,420)	(3,815)
Net income (loss)	$ 909	$ (7,941)
Net income (loss) per share attributable to common stockholders - basic		
Net income (loss) per share - basic	$ 0.09	$ (1.43)
Net loss per share attributable to common stockholders - diluted		
Net loss per share - diluted	$ (0.28)	$ (1.45)
Weighted average common shares outstanding - basic and diluted		
Basic	10,627,618	5,569,739
Diluted	13,389,014	6,707,939

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

	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 29,494	$ 41,920
Short-term investments	–	6,494
Total current assets	32,311	52,402
Operating lease right-of-use asset	3,047	3,191
Total assets	36,752	57,153
Total current liabilities	8,305	11,014
Warrant liabilities	2,282	18,396
Convertible debt and derivative liability	13,275	11,522
Operating lease liability, long term	3,332	3,326
Total liabilities	27,194	44,258
Total stockholders' equity	9,558	12,895
Total liabilities and stockholders' equity	$ 36,752	$ 57,153

Source: Scynexis