August 10, 2020

SCYNEXIS Reports Second Quarter 2020 Financial Results and Provides Company Update

In July, SCYNEXIS announced that it had successfully conducted pre-NDA meetings with the FDA regarding ibrexafungerp for the treatment of Vulvovaginal Candidiasis (VVC) more commonly known as vaginal yeast infection. NDA submission for this indication remains on track for Q4 2020.

In July, SCYNEXIS held an investor event with two key opinion leaders (KOLs) to discuss patient perspectives, unmet needs and treatment options in VVC, as well as the related commercial opportunity. This event followed the successful completion of the Phase 3 VANISH program evaluating oral ibrexafungerp 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 supplemental NDA submission anticipated in the second half of 2021.

JERSEY CITY, N.J., Aug. 10, 2020 (GLOBE NEWSWIRE) -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company pioneering innovative medicines to overcome and prevent difficult-to-treat and drug resistant infections, today reported financial results for the quarter ended on June 30, 2020 and provided an update on recent clinical and corporate developments.

“We have recently achieved some key milestones with the successful completion of our pivotal VANISH Phase 3 program evaluating oral ibrexafungerp for the treatment of vaginal yeast infections, followed by productive pre-NDA meetings with the FDA,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “In both our VANISH Phase 3 trials, ibrexafungerp treatment resulted in clinically meaningful improvement and statistically significantly greater cure rates when compared to placebo, and we remain on track to submit our NDA for the treatment of vaginal yeast infections in the fourth quarter of this year, setting us up for a potential regulatory approval in mid-2021. I am extremely proud of our team’s commitment to advancing this program as we transition SCYNEXIS to a fully integrated drug development and commercial company with an initial focus on vaginal yeast infections.”

Ibrexafungerp Update

Ibrexafungerp achieved superiority over placebo with a high degree of statistical significance on key study endpoints required for regulatory approval for the treatment of VVC in both VANISH pivotal trials. The two VANISH studies are among the first placebo-controlled trials of an antifungal agent in VVC. The results of these studies provide evidence of ibrexafungerp’s robust and clinically meaningful efficacy with no safety signals identified. Below are the top-line efficacy results of the VANISH pivotal trials:

(mITT)	VANISH-306 IBX 300mg BID (n=188) (%)	VANISH-306 Placebo (n=84) (%)	VANISH-303 IBX 300mg BID (n=188) (%)	VANISH-303 Placebo (n=98) (%)
Primary Endpoint				
Clinical Cure (0 S&S) at Day 10	63.3*	44.0*	50.5**	28.6**
Secondary Endpoints				
Mycological Eradication at Day 10	58.5**	29.8**	49.5**	19.4**
Clinical Improvement (S&S ≤1) at Day 10	72.3*	54.8*	64.4**	36.7**
Complete Symptom Resolution at Day-25 Follow Up	73.9**	52.4**	59.6*	44.9**
* p value ≤ 0.01 ** p value ≤ 0.001				

In both VANISH pivotal trials, oral ibrexafungerp was generally well-tolerated. Below is a summary of the higher frequency treatment-emergent adverse events (TEAEs) of the VANISH pivotal trials:

	VANISH-306 IBX 300mg BID (n=298) (%)	VANISH-306 Placebo (n=151) (%)	VANISH-303 IBX 300mg BID (n=247) (%)	VANISH-303 Placebo (n=124) (%)
Treatment-Emergent Adverse Events				
Diarrhea/Loose stool	9.4	0.7	25.5	6.5
Nausea	8.4	2.6	16.2	5.6
Abdominal Pain	2.7	1.3	6.9	2.4

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

  Ibrexafungerp has the potential to address vaginal yeast infections across a broad range of patients and could be an ideal treatment option for the many patients for whom current treatment options are suboptimal. With over six million women experiencing a yeast infection each year in the U.S., VVC is an under-appreciated, under-reported, and under-served women's health condition. There are over 15.4 million prescriptions written for VVC in the U.S. annually, all of which belong to a single drug class, the azoles. There has been no new oral treatment for VVC in over 25 years, and we believe health care providers are eager for a novel alternative to treat their patients.

  Ibrexafungerp, if approved, would be the first and only oral, non-azole treatment for vaginal yeast infections. SCYNEXIS believes that ibrexafungerp's unique combination of features, including its novel class, oral dosing, broad-spectrum, and fungicidal activity in all *Candida* species (*albicans* and non-*albicans*) including fluconazole resistant strains, will differentiate it from competing products.

- **SCYNEXIS recently announced the successful completion of pre-NDA meetings with U.S. Food and Drug Administration (FDA) on ibrexafungerp for the treatment of VVC**. The purpose of the meetings was to discuss and confirm the clinical, non-clinical and chemistry, manufacturing and controls (CMC) requirements for SCYNEXIS's proposed NDA submission and ensure that all elements of submission are met. SCYNEXIS submitted a pre-NDA briefing document to the FDA ahead of the meetings. Based on FDA feedback, SCYNEXIS believes its regulatory package will be sufficient to support an NDA submission of ibrexafungerp to the FDA for the treatment of VVC in the fourth quarter of this year.

- **SCYNEXIS plans to present top-line efficacy and safety results from its Phase 3 VANISH-303 dataset at the Infectious Diseases Society for Obstetrics and Gynecology (IDSOG) virtual conference. VANISH-306 data will be presented at a future scientific conference.**

- **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).**

- **Enrollment is ongoing in the Phase 2 SCYNERGIA study for patients with invasive aspergillosis** and pre-clinical activities are also ongoing in the development of a liposomal intravenous formulation of ibrexafungerp.

- **Data presentations.** SCYNEXIS continues to educate the scientific community about ibrexafungerp's clinical potential against a number of pathogens. On July 14, SCYNEXIS held an investor event featuring two KOLs Barbara Dehn, a nurse practitioner who specializes in women's health, and Caroline Mitchell, M.D., an Associate Professor, Obstetrics, Gynecology and Reproductive Biology and Director, Vulvovaginal Disorders Program at Massachusetts General Hospital. The two KOLs provided insight into the patient experience with VVC, the current VVC treatment landscape and unmet needs, and our management team provided an overview of the commercial opportunity in this indication. A replay of the event is available at https://ir.scynexis.com/ir-calendar/detail/3032/key-opinion-leader-discussion.

- In July 2020, SCYNEXIS presented data from an interim analysis of the Phase 3 FURI trial in patients with fungal infections that are refractory or resistant to standard of care as well as data from three preclinical studies demonstrating ibrexafungerp's broad-spectrum antifungal activity at the American Society for Microbiology (ASM) Microbe Online. In June 2020, SCYNEXIS also presented at the BIO Digital International Convention and provided an overview of SCYNEXIS, its progress towards transitioning to a fully integrated commercial-stage organization, and ibrexafungerp's clinical potential. Some of the posters presented are available at https://www.scynexis.com/news-media/press-releases/detail/215/scynexis-announces-four-posters-presented-at-asm-microbe.

Corporate Developments Subsequent to June 30, 2020

- On July 17, 2020, SCYNEXIS executed a 1-for-10 reverse split of its issued and outstanding common stock. As of August 1, 2020, there are 10.6 million shares outstanding, and 100 million authorized shares available.

Second Quarter Financial Results

Cash, cash equivalents and short-term investments totaled $37.6 million as of June 30, 2020, compared to $48.4 million in cash, cash equivalents, and short-term investments at December 31, 2019.

For the three months ended June 30, 2020, research and development expense of $8.5 million was comparable with the research and development expense for the three months ended June 30, 2019. During the three months ended June 30, 2020, SCYNEXIS incurred an increase of $0.5 million in chemistry, manufacturing, and controls (CMC) costs, an increase of $0.3 million in regulatory expense, and a net increase in other research and development expenses of $0.6 million, partially offset by a decrease of $1.4 million in clinical development costs.

Selling, general and administrative expenses for the quarter ended June 30, 2020 increased to $3.4 million from $2.8 million for the quarter ended June 30, 2019. The increase of $0.6 million, or 21%, was primarily driven by a $0.3 million increase in professional fees and commercial related expenses.

Total other income was $2.3 million for the quarter ended June 30, 2020, compared to total other income of $2.8 million for the quarter ended June 30, 2019. During the quarter ended June 30, 2020 and 2019, SCYNEXIS recognized non-cash gains of $3.6 million and $2.0 million, respectively, on the fair value adjustment of the warrant liabilities and during the quarter ended June 30, 2020 and 2019, recognized non-cash gains of $0.7 million and $1.3 million on the fair value adjustment of the derivative liabilities, respectively.

Net loss for the quarter ended June 30, 2020 was $6.4 million, or ($0.64) per basic and diluted share, compared to a net loss of $8.4 million, or ($1.58) per basic and diluted share, for the quarter ended June 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 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 SCYNEXIS remains on track to submit its NDA for the treatment of vaginal yeast infections in the fourth quarter of this year, and that SCYNEXIS anticipates top-line results and the submission of a supplemental NDA for recurrent VVC in the second half of 2021. 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; 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 Form 10-Q 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 June 30,	
	2020	**2019**

Revenue	$ –	$ 57
Operating expenses:		
Research and development	8,469	8,474
Selling, general and administrative	3,357	2,779
Total operating expenses	11,826	11,253
Loss from operations:	(11,826)	(11,196)
Other (income) expense:		
Loss on extinguishment of debt	806	231
Amortization of debt issuance costs and discount	321	373
Interest income	(36)	(233)
Interest expense	319	209
Other income	(60)	–
Other expense	602	–
Warrant liabilities fair value adjustment	(3,560)	(2,049)
Derivative liabilities fair value adjustment	(693)	(1,324)
Total other (income) expense	(2,301)	(2,793)
Loss before taxes	(9,525)	(8,403)
Income tax benefit	(3,144)	–
Net loss	$ (6,381)	$ (8,403)
Net loss per share - basic and diluted	$ (0.64)	$ (1.58)
Weighted average common shares outstanding - basic and diluted	10,009,614	5,327,766

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

	June 30, 2020	December 31, 2019
Cash and cash equivalents	$ 34,021	$ 41,920
Short-term investments	3,594	6,494
Total current assets	40,567	52,402
Operating lease right-of-use asset	3,094	3,191
Total assets	45,267	57,153
Total current liabilities	7,316	11,014
Warrant liabilities	10,067	18,396
Convertible debt and derivative liability	18,254	11,522
Operating lease liability, long term	3,330	3,326
Total liabilities	38,934	44,258
Total stockholders' equity	6,333	12,895
Total liabilities and stockholders' equity	$ 45,267	$ 57,153

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Source: Scynexis