

# SCYNEXIS Reports Full Year 2019 Financial Results and Provides Company Update

- Oral ibrexafungerp continues to advance in multiple indications
- Nearing completion of Phase 3 VANISH program, evaluating oral ibrexafungerp for the treatment of Vulvovaginal Candidiasis (VVC), more commonly known as vaginal yeast infection; second of two studies (VANISH-306) has completed enrollment in the U.S. and Europe; anticipate top-line data early second quarter 2020 with NDA submission in second half of 2020
- Enrollment is ongoing in Phase 3 CANDLE study of oral ibrexafungerp for the prevention of recurrent vaginal yeast infections; anticipate top-line data and supplemental NDA submission in second half of 2021
- Enrollment continues in Phase 3 refractory invasive fungal infections (rIFI) program (FURI and CARES studies) of oral ibrexafungerp in severe and difficult-to-treat fungal infections, including multidrug-resistant *Candida auris*; recently expanded FURI study protocol

JERSEY CITY, N.J., March 11, 2020 (GLOBE NEWSWIRE) -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company pioneering innovative medicines to overcome and prevent difficult-to-treat and drug resistant infections, reported financial results for the year ended December 31, 2019, and provided an update on recent clinical and corporate developments.

"The significant progress made in 2019 advanced us several steps closer to our goal of bringing ibrexafungerp to millions of patients worldwide who are in need of new options to overcome and prevent serious fungal infections. We are conducting multiple late-stage clinical studies of oral ibrexafungerp in indications ranging from vaginal yeast infections, for which there's only one approved oral therapy, to the life-threatening *Candida auris* infections affecting patients in hospital settings with compromised immune systems," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "Ibrexafungerp represents a novel class of antifungals in a field in which no new class has been approved in nearly 20 years. We believe ibrexafungerp has the potential to become a leading antifungal therapy in both the community and hospital settings, particularly given the lack of innovation in the category, growing resistance to existing treatments, and evolution of new species that pose an urgent threat to the public."

## Ibrexafungerp Development Update

- **Announced positive top-line results for the Phase 3 VANISH-303 study and completion of enrollment in the Phase 3 VANISH-306 study, investigating the safety and efficacy of oral ibrexafungerp as a treatment for women with vaginal yeast infections.** In the VANISH-303 study, ibrexafungerp achieved superiority over placebo with high statistical significance ( $p \leq 0.001$ ) for the key endpoints required to support the New Drug Application (NDA) filing for this indication. Both the VANISH-303 and VANISH-306 studies achieved faster-than-expected enrollment, demonstrating both the expected market opportunity and SCYNEXIS's stated timeline to submit an NDA to the U.S. Food and Drug Administration (FDA) for the treatment of VVC in the second half of 2020.
- **Announced Special Protocol Assessment (SPA) agreement with FDA for Phase 3 CANDLE study, evaluating oral ibrexafungerp for the prevention of recurrent VVC, a condition with no FDA-approved therapies.** Enrollment is ongoing in this study and SCYNEXIS anticipates top-line data and supplemental NDA submission in the second half of 2021. An open-label sub-study within CANDLE will also explore ibrexafungerp's efficacy in patients who failed treatment with fluconazole.
- **Announced positive results from the second interim analysis of the ongoing Phase 3 open-label FURI study.** The study is evaluating oral ibrexafungerp as a salvage treatment in patients with difficult-to-treat mucocutaneous and invasive fungal infections that are refractory to or intolerant of current standards of care, or require a non-azole oral step-down therapy for treatment of azole-resistant *Candida* species. An independent Data Review Committee assessed the efficacy of oral ibrexafungerp in a second cohort of 21 treated patients from the FURI study. Together with the initial 20 patients reported in January 2019, the dataset consists of 41 patients analyzed to date. Efficacy was consistent across both interim analyses, as oral ibrexafungerp showed clinical benefits in 83% of patients (34 out of 41), with 23 patients achieving a complete or partial response and 11 patients a stable disease response. Of the 41 treated patients, only six did not

respond to ibrexafungerp treatment and one patient was considered indeterminate. The data will be presented at an upcoming scientific conference in the first half of 2020.

- **Amended the protocol for the ongoing Phase 3 open-label FURI study.** Under the amended study design, the protocol was expanded to include patients with complex fungal infections such as aspergillosis, coccidioidomycosis, histoplasmosis, blastomycosis and infections caused by other emerging fungi including yeasts and molds in addition to *Candida* infections. Maximum allowed treatment duration 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 (SoC) for certain infections.
- **Enrollment ongoing in Phase 3 open-label CARES study.** Enrollment continues in the CARES study for patients with *Candida auris* infections. The Centers for Disease Control and Prevention (CDC) recently declared *Candida auris*, an emerging, multidrug-resistant pathogen, an “Urgent Threat” to public health.
- **Enrollment ongoing in Phase 2 SCYNERGIA study.** Enrollment continues in the SCYNERGIA study for patients with invasive aspergillosis (IA) and SCYNEXIS recently amended the protocol to include transplanted patients, who are a well-known category at risk of fatal infection due to *Aspergillus*.
- **SCYNEXIS continues to explore development of IV formulation of ibrexafungerp.** While oral ibrexafungerp is progressing as a potentially valuable option to treat hospital-based invasive fungal infections, as recently shown in the second interim analysis from the FURI study, SCYNEXIS is developing an intravenous liposomal formulation of ibrexafungerp and will provide further updates on this program in the future.
- **SCYNEXIS continues to educate the scientific community about the broad clinical utility of ibrexafungerp.** SCYNEXIS attended 11 national and international scientific conferences with 30 oral and poster presentations. In 2019, a total of ten ibrexafungerp scientific publications were released.

## Corporate Highlights

- In December 2019, SCYNEXIS raised approximately \$35 million in a public offering of common stock and warrants. SCYNEXIS sold 38,888,889 shares of its common stock and warrants to purchase up to 38,888,889 shares of SCYNEXIS’s common stock. Additionally, the underwriters exercised an option to purchase 5,833,333 additional warrants. Based upon SCYNEXIS’s existing operating plan, SCYNEXIS believes that its existing cash and cash equivalents and short-term investments, and the sale of a portion of SCYNEXIS’s NOLs, will enable it to fund operating requirements past a potential Prescription Drug User Fee Act (PDUFA) date in mid-2021 for the treatment of VVC when SCYNEXIS expects the FDA to complete the review of the NDA and potentially approve ibrexafungerp for the treatment of VVC.
- In January 2020, SCYNEXIS entered into an agreement to sell a portion of its unused Net Operating Losses (NOLs) and R&D credits; SCYNEXIS expects to receive a cash receipt of approximately \$3.1 million.
- In December 2019, SCYNEXIS appointed Philippe Tinmouth to its Board of Directors. Mr. Tinmouth brings over 20 years of experience across multiple business development and alliance management roles.

## Full Year 2019 Financial Results

Cash, cash equivalents and short-term investments totaled \$48.4 million as of December 31, 2019, compared to \$44.2 million in cash, cash equivalents, and short-term investments at December 31, 2018.

Research and development expenses for the year ended December 31, 2019 increased to \$38.4 million from \$21.6 million for the year ended December 31, 2018. The increase of \$16.8 million, or 78.1%, was primarily driven by a milestone payment made in 2019 to Merck upon initiation of the Phase 3 VVC registration study, an increase of \$11.8 million in clinical development expenses, an increase of \$0.6 million in chemistry, manufacturing, and controls (CMC), and an increase of \$1.1 million in salary and personnel related costs, and a net increase of \$1.0 million in other research and development expenses, offset in part by a decrease of \$1.7 million in preclinical expenses.

Selling, general and administrative expenses for the year ended December 31, 2019 increased to \$10.6 million from \$8.7 million for the year ended December 31, 2018. The increase of \$2.0 million, or 22.7%, was primarily driven by a \$1.0 million increase in business development and commercial related costs, a \$0.6 million increase in professional fees, a \$0.4 million increase in salary and personnel related costs, and a net increase in other selling, general and administrative expenses of \$0.2 million, offset in part by a \$0.2 million charge for deferred offering costs recognized in 2018.

Total other expense was \$4.8 million for the year ended December 31, 2019, compared to total other income of \$10.8 million for the year ended December 31, 2018. The \$4.8 million in total other expense is primarily attributable to a \$4.5 million non-cash loss and a \$1.6 million non-cash gain recorded on the fair value adjustments of the warrant liabilities and derivative liability, respectively, for the year ended December 31, 2019.

Net loss for the year ended December 31, 2019 was \$53.7 million, or (\$0.96) per basic and diluted share, compared to a net loss of \$12.5 million, or (\$0.28) per basic and diluted share, for the year ended December 31, 2018.

### **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 called 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 invasive candidiasis (IC) (including candidemia), invasive aspergillosis (IA) and vulvovaginal candidiasis (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 and drug-resistant infections. 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 in the community setting 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](http://www.scynexis.com).

### **Forward Looking Statement**

Statements contained in this press release regarding expected future events or results, including but not limited to statements regarding SCYNEXIS's expectations on reporting top-line data and timing of NDA submissions, 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; 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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**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share data)

	<b>Years Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
Revenue	\$ 121	\$ 257
Operating expenses:		
Research and development	38,394	21,560
Selling, general and administrative	10,648	8,680
Total operating expenses	49,042	30,240
Loss from operations	(48,921 )	(29,983 )
Other expense (income):		
Loss on extinguishment of debt	1,045	-
Amortization of debt issuance costs and discount	1,171	428
Interest income	(805 )	(967 )
Interest expense	986	1,626
Other income	(538 )	-
Warrant liabilities fair value adjustment	4,497	(11,866 )
Derivative liability fair value adjustment	(1,567 )	-
Total other expense (income):	4,789	(10,779 )
<b>Loss before taxes</b>	(53,710 )	(19,204 )
Income tax benefit	-	6,736
<b>Net loss</b>	<b>\$ (53,710 )</b>	<b>\$ (12,468 )</b>
Net loss per share - basic and diluted	\$ (0.96 )	\$ (0.28 )
Weighted average common shares outstanding - basic and diluted	56,081,384	43,883,995

**SCYNEXIS, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands)

	<b>December 31, 2019</b>	<b>December 31, 2018</b>
Cash and cash equivalents	\$ 41,920	\$ 11,439
Short-term investments	6,494	32,718
Total current assets	52,402	51,463
Operating lease right-of-use asset	3,191	-
Total assets	57,153	53,170
Total current liabilities	11,014	5,877
Warrant liabilities	18,396	986
Loan payable expected to be refinanced	-	15,082
Convertible debt and derivative liability	11,522	-
Operating lease liability	3,362	-
Total liabilities	44,258	21,945
Total stockholders' equity	12,895	31,225
Total liabilities and stockholders' equity	\$ 57,153	\$ 53,170



Source: Scynexis