

March 14, 2019



# **SCYNEXIS Reports Full Year 2018 Financial Results and Provides Company Update**

**Phase 3 VANISH program underway, evaluating oral ibrexafungerp for the treatment of acute VVC; anticipate top-line data in the first half of 2020 with NDA submission in the second half of 2020**

**Oral ibrexafungerp continues to advance across multiple additional indications, including the prevention of recurrent VVC and invasive aspergillosis; recent positive preliminary FURI results showed clinical benefits in refractory invasive fungal infections**

**Raised \$16.0 million in March 2019 via sale of convertible debt to retire maturing term loan, enhancing already strong cash balance and extending cash runway past anticipated NDA submission in the second half of 2020**

JERSEY CITY, N.J., March 14, 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 year ended December 31, 2018, and provided an update on recent operational and clinical developments.

"We ended 2018 having accomplished meaningful progress across our ibrexafungerp clinical development programs, including positive results from our Phase 2b DOVE study evaluating the oral formulation of ibrexafungerp in the lead indication of vulvovaginal candidiasis," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "We fully intend to carry the momentum of 2018 throughout this year as we conduct our Phase 3 VANISH trials, where we anticipate top-line data in the first half of 2020 with a planned New Drug Application (NDA) submission in the second half of 2020."

Dr. Taglietti continued: "Progress also continues on the development of oral ibrexafungerp across multiple additional indications in severe, difficult-to-treat, hospital-based infections to address a significant unmet need for patients fighting life-threatening and often drug-resistant pathogens. Recently, we disclosed the positive results obtained with oral ibrexafungerp in a group of patients with fungal infections refractory to currently available treatments and we initiated the Phase 2 study in invasive aspergillosis. We remain focused on maximizing the broad clinical utility of ibrexafungerp and realizing the full potential of this first member of a new antifungal class."

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

referred to as triterpenoids, is being developed for oral and intravenous (IV) 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 only oral alternative to azoles for the treatment of VVC and prevention of recurrent VVC.

## **Ibrexafungerp Development Update**

- **Currently enrolling patients in the VANISH Phase 3 registration program evaluating the safety and efficacy of ibrexafungerp in patients with acute VVC. On track to initiate a planned Phase 3 trial of ibrexafungerp for the prevention of recurrent VVC in the first half of 2019.**
  - In January 2019, SCYNEXIS announced the initiation of the Phase 3 VANISH registration program following a positive end-of-phase 2 meeting with the U.S. Food and Drug Administration (FDA). The VANISH program is comprised of two Phase 3 clinical trials (approximately 350 patients each) designed to evaluate the efficacy of a one-day 600mg oral dose of ibrexafungerp versus placebo for the treatment of VVC. Top-line results from the study are anticipated in the first half of 2020. Pending successful completion of these two trials, SCYNEXIS plans to submit an initial NDA for oral ibrexafungerp for the treatment of VVC in the second half of 2020.
  - SCYNEXIS is on track to initiate a third Phase 3 clinical trial (approximately 350 patients) evaluating the safety and efficacy of oral 600mg ibrexafungerp, given once-a-month for six months, versus placebo for the prevention of recurrent VVC. Patients with a diagnosis of VVC and a history of at least three episodes of VVC in the past 12 months (including the current episode) will first receive standard-of-care (SoC) treatment for their active infection. Patients whose active infection has been successfully treated will be randomized to ibrexafungerp or placebo in a 1:1 ratio for the prevention phase of the trial.
  - These Phase 3 programs are designed to build on the positive top-line data reported from the Phase 2b DOVE study. This study demonstrated that the one-day 600mg ibrexafungerp oral dose selected for Phase 3 clinical evaluation was well-tolerated, with strong clinical and mycological activity, and showed potential for improved sustained effect versus fluconazole, the current SoC for VVC.
  - In May 2018, the FDA granted both Qualified Infectious Disease Product (QIDP) and Fast Track designations for the oral formulation of ibrexafungerp for the treatment of VVC and the prevention of recurrent VVC, which includes priority review and five years of additional exclusivity.
- **Progress continues on SCYNEXIS's strategy to expand the use of ibrexafungerp in severe, difficult-to-treat, fungal infections.**
  - In January 2019, SCYNEXIS announced interim results from the first 20 patients enrolled in the FURI study, a global, open-label study evaluating oral ibrexafungerp as a salvage treatment in patients with difficult-to-treat refractory or resistant invasive fungal infections. Oral ibrexafungerp demonstrated a clinical benefit in 17 of the 20 patients, with 11 patients achieving a complete or partial response and six patients achieving a stable disease response. Oral ibrexafungerp was well-tolerated, with the most common treatment-related adverse events being gastrointestinal. There were no deaths due to progressive fungal disease and no safety signals warranting changes in the study. These

preliminary results support continued patient enrollment in the FURI study to build toward a future NDA submission and potential approval through the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD). Enrollment in the study continues to progress, with 32 sites now active in the U.S. and Europe.

- In October 2018, SCYNEXIS dosed the first patient in the Phase 3, multi-center (U.S. and India), open-label, single-arm study evaluating the efficacy, safety and tolerability of oral ibrexafungerp for the treatment of *Candida auris* infections (CARES study). *C. auris* has been classified by the Centers for Disease Control and Prevention (CDC) as a serious global health threat, as it can be multidrug-resistant, with a mortality rate of up to 60%. Enrollment is ongoing with several patients currently enrolled.
- In the fourth quarter of 2018, SCYNEXIS initiated a Phase 2 study (SCYNERGIA study) of oral ibrexafungerp in combination with voriconazole for the treatment of invasive aspergillosis. This study was initiated following improved outcomes and survival rates observed in preclinical models of pulmonary aspergillosis using the combination of oral ibrexafungerp with azole therapy.
- **SCYNEXIS continues to explore development of IV formulation of ibrexafungerp.** While oral ibrexafungerp is progressing as a potential valuable option to treat hospital-based invasive fungal infections, as recently shown in the preliminary results from the FURI study, the company continues with the development of the intravenous liposomal formulation of ibrexafungerp and will provide further updates on this program in the future.
- **Presentation of new preclinical data in support of prophylactic use of oral ibrexafungerp.** In February 2019, SCYNEXIS announced the presentation of a poster at the upcoming Superbugs and Superdrugs 2019 conference. The poster, titled "Activity of oral ibrexafungerp in murine models of *Pneumocystis pneumonia* (PCP)," highlights the results from multiple preclinical studies that evaluated oral ibrexafungerp versus trimethoprim/sulfamethoxazole, the current SoC for PCP. Oral ibrexafungerp demonstrated strong activity against PCP in these models, as determined by a reduction in organism burden and improved survival. These results warrant further investigation of ibrexafungerp for both the prevention and treatment of PCP, a potentially life-threatening infection that occurs in vulnerable immunocompromised individuals, including those undergoing solid organ and stem cell transplants.

## Corporate Update

- **In March 2019, SCYNEXIS completed the sale of a \$16.0 million convertible unsecured senior note in a private placement to Puissance Capital.** The sale of the convertible note provides desired funds in a less dilutive manner than typical equity offerings. SCYNEXIS used the proceeds to retire in full the previous term loan, strengthening near-term cash flows and extending the Company's cash runway past an anticipated NDA submission in the second half of 2020.
- **United States Adopted Names (USAN) Council selected "Ibrexafungerp" as non-proprietary name for SCY-078.** In February 2019, the USAN Council, in consultation with the World Health Organization's (WHO) International Nonproprietary Names (INN) Expert Committee, selected ibrexafungerp as the non-proprietary name for SCY-078. The USAN Council, by working closely with the INN Programme of the WHO and various national nomenclature groups, aims for global standardization and unification of drug nomenclature to ensure that drug information is communicated accurately and

unambiguously. In July 2018, the WHO INN group created the new stem, "-fungerp," indicating that ibrexafungerp is different and unique to any previously-approved antifungal drug, and the first member of a new triterpenoid drug class. Ibrexafungerp has the potential to be the first new antifungal class approved in the last 20 years.

- **In January 2019, SCYNEXIS announced the appointment of Armando Anido to its Board of Directors.** Mr. Anido currently serves as Chairman and Chief Executive Officer of Zynerva Pharmaceuticals (NASDAQ: ZYNE), a role he has held since October 2014, and has more than 30 years of executive leadership experience in the biopharmaceutical industry. The addition of Mr. Anido to an experienced Board provides invaluable operational and commercial expertise as SCYNEXIS prepares to potentially submit an NDA in the second half of 2020.
- **In January 2019, SCYNEXIS completed the sale of a portion of its Net Operating Losses (NOLs) and received a cash receipt of \$6.7 million.** This sale was structured through the New Jersey Technology Business Tax Certificate Transfer (NOL) Program, which 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 transaction resulted in a pro forma cash balance of \$51 million as of January 3, 2019.

## Full Year 2018 Financial Results

Cash, cash equivalents and short-term investments totaled \$44.2 million as of December 31, 2018.

Research and development expenses increased to \$21.6 million for the year ended December 31, 2018, compared to \$18.3 million for the year ended December 31, 2017. The increase of \$3.2 million, or 17.6%, was primarily driven by an increase of \$2.9 million in clinical development, an increase of \$1.3 million in chemistry, manufacturing, and controls (CMC), and an increase of \$0.8 million in salary and personnel related costs, offset in part by a decrease of \$1.5 million in consulting fees and a net decrease of \$0.3 million in other research and development expenses.

Selling, general and administrative expenses increased to \$8.7 million in 2018, compared with \$8.3 million in 2017. The increase of \$0.4 million, or 5.2%, in 2018, was primarily driven by the \$0.2 million charge for deferred offering costs recognized during the year ended December 31, 2018.

Total other income was \$10.8 million in 2018, compared to other income of \$1.3 million in 2017 due to a \$11.9 million non-cash gain recorded on the adjustment in the fair value of the warrant liabilities.

Income tax benefit increased to \$6.7 million in 2018, compared to zero in 2017, due to the \$6.7 million sale of a portion of SCYNEXIS's NOLs through the New Jersey Technology Business Tax Certificate Transfer (NOL) Program.

Net loss for 2018 was \$12.5 million, or \$0.28 per share. This compares with a net loss for 2017 of \$25.1 million, or \$0.94 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, 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* and *Aspergillus* species. 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 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.**  
**STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share data)

	Years Ended December 31,	
	2018	2017
Revenue	\$ 257	\$ 257
Operating expenses:		
Research and development, net	21,560	18,326
Selling, general and administrative	8,680	8,251
Total operating expenses	30,240	26,577
Loss from operations	(29,983)	(26,320)
Other expense (income):		
Amortization of debt discount	428	400
Interest income	(967)	(386)
Interest expense	1,626	1,455
Warrant liabilities fair value adjustment	(11,866)	(2,729)
Total other income:	(10,779)	(1,260)
<b>Loss before taxes</b>	(19,204)	(25,060)
Income tax benefit	6,736	-
<b>Net loss</b>	<b>\$ (12,468)</b>	<b>\$ (25,060)</b>
Net loss per share – basic and diluted	\$ (0.28)	\$ (0.94)
Weighted average common shares outstanding – basic and diluted	43,883,995	26,746,322

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

	December 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 11,439	\$ 11,469
Short-term investments	32,718	32,424
Total current assets	51,463	44,960
Total assets	53,170	45,850
Loan payable, current portion	-	4,349
Total current liabilities	5,877	10,144
Loan payable expected to be refinanced	15,082	10,303
Total liabilities	21,945	24,440
Total stockholders' equity	31,225	21,410
Total liabilities and stockholders' equity	\$ 53,170	\$ 45,850

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