

March 29, 2021



## SCYNEXIS Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Corporate Update

- *FDA accepted SCYNEXIS' New Drug Application (NDA) for oral ibrexafungerp for the treatment of vaginal yeast infections, conditionally approved the brand name Brexafemme™, and granted priority review with a PDUFA target action date of June 1, 2021*
- *SCYNEXIS partnered with Amplity Health, a leading global contract commercialization organization, in connection with anticipated U.S. launch of Brexafemme in the second half of 2021, with a portion of Amplity's direct fees deferred*
- *SCYNEXIS out-licensed the rights to ibrexafungerp for the Greater China region to Hansoh Pharma, resulting in a \$10 million upfront payment and the potential for up to \$112 million in additional milestones plus royalties on sales*
- *Enrollment is complete in the Phase 3 CANDLE study of oral ibrexafungerp for the prevention of recurrent vaginal yeast infections; last-patient / last-visit expected by the end of the year with top-line results and a supplemental NDA submission anticipated in the first half of 2022, resulting in a potential approval in late 2022*
- *SCYNEXIS announced positive results from interim analyses of ongoing Phase 3 studies (FURI and CARES), showing oral ibrexafungerp's ability to treat severe fungal infections in the hospital setting, including those caused by Candida auris*
- *Based on cash balance at December 31<sup>st</sup> and subsequent Q1 2021 upfront payment from Hansoh, SCYNEXIS is in a strong financial position to execute on its plans with a projected cash runway into 2023*

JERSEY CITY, N.J., March 29, 2021 (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 fourth quarter ended on December 31, 2020 and provided an update on recent clinical and corporate developments.

"This has been an extremely active period for our team as we build out the commercial infrastructure in preparation for the anticipated approval of Brexafemme for vaginal yeast infections on June 1, 2021, while advancing the hospital clinical programs in both the oral and IV formulations," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "Between our successful \$85 million public offering in December and our recent \$10 million upfront payment in connection with our partnership with Hansoh Pharma in the

Greater China region, we have also fortified our balance sheet, with our cash runway projected into 2023.”

### **Ibrexafungerp Update**

- **SCYNEXIS announced on December 7, 2020 that its NDA for oral ibrexafungerp for the treatment of vulvovaginal candidiasis (VVC), also known as vaginal yeast infection, was accepted for filing by the U.S. Food and Drug Administration (FDA).** The FDA has granted this application Priority Review and set a Prescription Drug User Fee Act (PDUFA) target action date of June 1, 2021. Additionally, the FDA has communicated that it is not currently planning to hold an advisory committee meeting to discuss the application.
- **Enrollment is complete 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.** SCYNEXIS expects the last-patient / last-visit by the end of 2021 with top-line results and a supplemental NDA submission anticipated in the first half of 2022, resulting in a potential approval in late 2022.
- **Enrollment is ongoing in SCYNEXIS’s refractory invasive fungal infections (rIFI) program, which comprises two open-label Phase 3 studies (FURI and CARES).** On March 2, 2021 SCYNEXIS presented positive data from its third interim analysis of the FURI study and first interim analysis of the CARES study, showing oral ibrexafungerp’s ability to treat severe fungal infections in the hospital setting. Consistent with two prior interim analyses, the FURI results confirm positive clinical activity of oral ibrexafungerp in patients with difficult-to-treat, severe, mucocutaneous and invasive fungal infections, including those caused by resistant strains. In total, oral ibrexafungerp showed clinical benefits in 64 out of 74 patients (86.5%), with 46 patients achieving a complete or partial response and 18 patients with stable disease. The first interim analysis of CARES study showed strong clinical activity of oral ibrexafungerp in patients with invasive candidiasis and candidemia due to *Candida auris*, a high-mortality infection classified by Centers for Disease Control and Prevention (CDC) as an urgent threat to public health, with 8 out of 10 patients (80.0%) experiencing a complete response. The results support continued enrollment in both open-label Phase 3 studies, with potential future submissions under the LPAD regulatory pathway.
- **Dosing is ongoing in Phase 1 testing of the liposomal IV formulation of ibrexafungerp.** Based on promising pre-clinical data of SCYNEXIS’s liposomal IV formulation of ibrexafungerp, SCYNEXIS is conducting a Phase 1, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, and pharmacokinetics of the IV liposomal formulation of ibrexafungerp in healthy subjects. The study is being conducted in South Africa and dosing started in March 2021.
- **Enrollment is ongoing in the Phase 2 SCYNERGIA study for patients with invasive aspergillosis.** SCYNERGIA is evaluating oral ibrexafungerp in combination with voriconazole for the treatment of patients with this high-mortality infection. Top-line data from this study is expected by the end of 2021.

### **Corporate Developments and Subsequent Events**

- On December 2, 2020, SCYNEXIS amended its license agreement with Merck, eliminating two cash milestone payments that it would have paid to Merck upon the first filing of an NDA and first marketing approval in the U.S., anticipated in June 2021 for SCYNEXIS's NDA for ibrexafungerp for the treatment of VVC. Such cash milestone payments would have been creditable against future royalties owed to Merck on net sales of ibrexafungerp. With the amendment, these milestones will not be paid in cash and, accordingly, credits will not accrue. SCYNEXIS will also forfeit the credits against future royalties that it had accrued from a prior milestone payment already paid to Merck.
- On December 22, 2020, SCYNEXIS announced the closing of an \$85 million public offering of common stock, prefunded warrants and warrants.
- On February 11, 2021, SCYNEXIS entered into a licensing and strategic partnership agreement for ibrexafungerp with Hansoh Pharmaceutical that covers the Greater China region. SCYNEXIS received a \$10 million upfront payment and is eligible to receive development and commercial milestone payments of up to \$112 million, plus low double-digit royalties on net sales.
- On February 23, 2021, SCYNEXIS announced that it has partnered with Amplify Health, a leading global contract commercialization organization, to support the anticipated U.S. commercialization of Brexafemme, the conditionally FDA-approved brand name for ibrexafungerp for vaginal yeast infections, in the second half of 2021. SCYNEXIS will utilize Amplify's commercial execution expertise and resources for sales force, remote engagement, training, market access and select operations services.

## **Full Year 2020 Financial Results**

Cash and cash equivalents totaled \$93.0 million as of December 31, 2020, compared to \$48.4 million in cash, cash equivalents, and short-term investments at December 31, 2019.

Research and development expense for the year ended December 31, 2020 decreased to \$36.5 million from \$38.4 million for the year ended December 31, 2019. The decrease of \$1.9 million, or 4.9%, was primarily driven by a milestone payment made in 2019 to Merck upon initiation of the Phase 3 VVC registration study, a decrease of \$4.2 million in clinical development expense, a decrease of \$1.0 million in preclinical expense, offset in part by an increase of \$4.5 million in chemistry, manufacturing, and controls (CMC), an increase of \$1.1 million in salary and consulting related costs, an increase of \$1.1 million in regulatory expense, and a net increase in other research and development expense of \$0.6 million.

Selling, general and administrative expenses for the year ended December 31, 2020 increased to \$14.6 million from \$10.6 million for the year ended December 31, 2019. The increase of \$4.0 million, or 37.4%, was primarily driven by a \$1.5 million increase in commercial and business development expense, a \$1.3 million increase in other professional service expense, a \$0.9 million increase in salary and other compensation related costs, and a net increase in other selling, general and administrative expenses of \$0.3 million.

Total other expense was \$7.2 million for the year ended December 31, 2020, compared to

total other expense of \$4.8 million for the year ended December 31, 2019. During the year ended December 31, 2020 and 2019, SCYNEXIS recognized non-cash expenses of \$5.2 million and \$4.5 million, respectively, on the fair value adjustment of the warrant liabilities and during the year ended December 31, 2020 and 2019, recognized non-cash gains of \$2.3 million and \$1.6 million on the fair value adjustment of the derivative liabilities, respectively.

Net loss for the year ended December 31, 2020 was \$55.2 million, or (\$5.15) per basic and diluted share, compared to a net loss of \$53.7 million, or (\$9.58) per basic and diluted share for the year ended December 31, 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 under regulatory review for the treatment of vaginal yeast infection, also known as vulvovaginal candidiasis (VVC), and in late-stage development for multiple indications, including life-threatening fungal infections caused primarily by *Candida* (including *C. auris*) and *Aspergillus* species in hospitalized patients. 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 accepted a New Drug Application for ibrexafungerp for the treatment of VVC and granted a Prescription Drug User Fee Act (PDUFA) action date of June 1, 2021. It also granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the IV and oral formulations of ibrexafungerp for the indications of invasive candidiasis (IC) (including candidemia) and invasive aspergillosis (IA), 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, currently under regulatory review for the treatment of vaginal yeast infection, also known as vulvovaginal candidiasis (VVC), and in late stage development for the treatment of 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 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 anticipated approval and commercial launch of ibrexafungerp for the treatment of VVC;

expectations for progression of clinical trials, reporting clinical data, submitting NDAs and obtaining potential approvals; and SCYNEXIS's projected cash runway into 2023. 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 approval 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 and potential commercialization of ibrexafungerp for the treatment of VVC. 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.

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

	Years Ended December 31,	
	2020	2019
Revenue	\$ -	\$ 121
Operating expenses:		
Research and development	36,522	38,394
Selling, general and administrative	14,627	10,648
Total operating expenses	51,149	49,042
Loss from operations	(51,149)	(48,921)
Other expense (income):		

Loss on extinguishment of debt	1,766	1,045
Amortization of debt issuance costs and discount	1,201	1,171
Interest income	(189)	(805)
Interest expense	1,181	986
Other income	(334)	(538)
Other expense	602	–
Warrant liabilities fair value adjustment	5,214	4,497
Derivative liability fair value adjustment	(2,257)	(1,567)
Total other expense (income):	7,184	4,789
<b>Loss before taxes</b>	(58,333)	(53,710)
Income tax benefit	3,148	–
<b>Net loss</b>	<u>\$ (55,185)</u>	<u>\$ (53,710)</u>
Net loss per share - basic and diluted	<u>\$ (5.15)</u>	<u>\$ (9.58)</u>
Weighted average common shares outstanding - basic and diluted	10,720,211	5,608,138

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

	<b>December 31, 2020</b>	<b>December 31, 2019</b>
Cash and cash equivalents	\$ 93,041	\$ 41,920
Short-term investments	–	6,494
Total current assets	98,206	52,402
Operating lease right-of-use asset	2,999	3,191
Total assets	102,536	57,153
Warrant liabilities, current	17,564	–
Total current liabilities	26,396	11,014
Warrant liabilities	33,592	18,396
Convertible debt and derivative liabilities	16,516	11,522
Operating lease liability, non-current	3,274	3,326
Total liabilities	79,778	44,258
Total stockholders' equity	22,758	12,895
Total liabilities and stockholders' equity	102,536	57,153



Source: Scynexis