

May 17, 2021



SCYNEXIS Reports First Quarter 2021 Financial Results and Provides Corporate Update

- *Secured non-dilutive funding of approximately \$35 million thus far in 2021, including licensing payments from Hansoh Pharma, the first tranche from a term loan agreement with Hercules and Silicon Valley Bank, and the monetization of the 2020 New Jersey NOLs*
- *Appointed Christine Coyne as Chief Commercial Officer to lead the launch of ibrexafungerp (Brexafemme®) for the treatment of vaginal yeast infections, following expected approval by June 1st*
- *Began dosing patients in a Phase 1 trial of the IV formulation of ibrexafungerp*
- *Further strengthened balance sheet and projected cash runway into 2023*

JERSEY CITY, N.J., May 17, 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 first quarter ended on March 31, 2021 and provided an update on recent clinical and corporate developments.

“Our team is executing on all cylinders as we approach our June 1, 2021 PDUFA for Brexafemme,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “So far this year, we have received a total of approximately \$35 million in non-dilutive funding, which is adequate to support our Brexafemme U.S. launch in the second half of the year while further extending our cash runway into 2023. We are also advancing the development of ibrexafungerp in the hospital setting, including our new IV formulation currently in Phase 1. With ibrexafungerp poised to become the first new antifungal class approved in over 20 years, we believe that the approval of the VVC indication may represent just the first step in the larger build-out of our antifungal franchise.”

Ibrexafungerp Update

- **Remain on track for anticipated June 1st approval of ibrexafungerp for the treatment of VVC and commercial launch in the second half of 2021.** SCYNEXIS is currently in discussions with the FDA to finalize its recommended wording for different sections of the drug’s Prescribing Information to provide adequate information to prescribers.
- **Dosing is ongoing in Phase 1 testing of the liposomal IV formulation of ibrexafungerp.** Based on promising pre-clinical data of our 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 began in March 2021.

- **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 our 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. 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 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.
- **Ibrexafungerp Phase 3 data were presented at a key medical conference, reporting efficacy in non-*albicans* *Candida* (NAC) and severe patients with vulvovaginal candidiasis infections.** On April 30, SCYNEXIS presented posters on two data sets from SCYNEXIS's Phase 3 VANISH program demonstrating the therapeutic potential of ibrexafungerp at the 2021 American College of Obstetricians and Gynecologists (ACOG) Annual Meeting that took place virtually from April 30-May 2, 2021. The data highlighted ibrexafungerp efficacy in treating patients with NAC, which was comparable to that of the total patient population enrolled in the trial. Additionally, ibrexafungerp was shown to be efficacious in patients with severe VVC, and may provide a treatment alternative where currently available therapies may not be satisfactory.

Corporate Developments and Subsequent Events

- On February 11, 2021, SCYNEXIS entered into a licensing and strategic partnership agreement for ibrexafungerp with Hansoh Pharmaceutical that covers the Greater China region. So far SCYNEXIS received \$11 million in upfront and milestone payments and is eligible to receive additional development and commercial milestone payments of up to \$111 million, plus 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.

- In May 2021, SCYNEXIS entered into an agreement with a third party to sell a portion of its unused 2020 New Jersey NOLs for approximately \$4.2 million.
- On May 10, 2021, SCYNEXIS granted stock options to three new employees to purchase an aggregate of 15,000 shares of SCYNEXIS common stock at a per share exercise price of \$6.50, the closing trading price on May 10, 2021. Each option has a ten-year term, with one-fourth of the shares subject to the option vesting on the one-year anniversary of the employee's first date of employment and the remainder vesting in equal monthly installments for thirty-six months thereafter, provided the employee continues to provide service to SCYNEXIS. The stock options were granted pursuant to SCYNEXIS's 2015 Inducement Award Plan, as amended in April 2021, which was adopted by the SCYNEXIS's board of directors in March 2015 under Rule 5635(c)(4) for equity grants to induce new employees to enter into employment with SCYNEXIS.
- On May 11, 2021, SCYNEXIS announced the appointment of Christine Coyne as its Chief Commercial Officer to lead the anticipated U.S launch and commercialization of Brexafemme. She brings to the team deep anti-infective commercial expertise across hospital and community settings.
- On May 13, 2021, SCYNEXIS entered into a loan agreement with Hercules Capital, Inc. and Silicon Valley Bank for an aggregate principal amount of \$60.0 million. Under the terms of the loan agreement, SCYNEXIS received an initial tranche of \$20.0 million from the lenders on the Closing Date and is eligible to receive an additional \$10.0 million upon FDA approval of ibrexafungerp for the treatment of vaginal yeast infections. Subsequent cash injections will be available upon achieving certain milestones.

First Quarter 2021 Financial Results

Cash and cash equivalents totaled \$92.0 million on March 31, 2021, compared to \$93.0 million in cash and cash equivalents on December 31, 2020.

Research and development expense for the three months ended March 31, 2021 decreased to \$6.9 million from \$9.9 million for the three months ended March 31, 2020. The decrease of \$2.9 million, or 30%, for the three months ended March 31, 2021, was primarily driven by a decrease of \$2.1 million in clinical development expense, a decrease of \$0.9 million in chemistry, manufacturing, and controls (CMC) expense, and a decrease of \$0.5 million in preclinical expense, offset in part by an increase in salary related costs of \$0.3 million and a net increase in other research and development expense of \$0.3 million.

Selling, general & administrative expense for the three months ended March 31, 2021 increased to \$6.7 million from \$2.6 million for the three months ended March 31, 2020. The increase of \$4.1 million, or 156%, for the three months ended March 31, 2021 was primarily driven by a \$1.7 million increase in commercial related expense, an increase of \$1.0 million

in business development expense, an increase of \$0.5 million in expense associated with increased information technology costs, and an increase of \$0.3 million salary related costs.

Total other expense was \$2.0 million for the three months ended March 31, 2021, compared to total other income of \$5.5 million for the three months ended March 31, 2020. During the three months ended March 31, 2021 and 2020, SCYNEXIS recognized non-cash income of \$1.3 million and \$4.8 million, respectively, on the fair value adjustment of the warrant liabilities and during the three months ended March 31, 2021 and 2020, recognized non-cash expense of \$0.1 million and non-cash gains of \$0.7 million on the fair value adjustment of the derivative liabilities, respectively.

Net loss for the three months ended March 31, 2021 was \$4.7 million, or (\$0.18) per basic and (\$0.23) per diluted share, compared to a net loss of \$7.0 million, or (\$0.72) per basic and diluted share for the three months ended March 31, 2020.

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.

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 the adequacy of SCYNEXIS' funding to support its Brexafemme U.S. launch in the second half of the year while further extending its cash runway into 2023, timelines for last-patient / last-visit, reporting top-line results, a potential supplemental NDA submission and potential 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' ability to successfully develop and obtain FDA approval for ibrexafungerp; unexpected delays may occur in the timing of acceptance by the FDA of an NDA submission; the expected costs of studies and when they might begin or be concluded; SCYNEXIS' need for additional capital resources; and SCYNEXIS' reliance on third parties to conduct SCYNEXIS' clinical studies. These and other risks are described more fully in SCYNEXIS' 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, including 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 March	
	31,	
	2021	2020
Revenue	\$ 12,050	\$ -
Operating expenses:		

Research and development	6,948	9,866
Selling, general and administrative	6,696	2,613
Total operating expenses	13,644	12,479
Loss from operations:	(1,594)	(12,479)
Other expense (income):		
Loss on extinguishment of debt	2,725	-
Amortization of debt issuance costs and discount	256	278
Interest income	(7)	(147)
Interest expense	214	210
Other income	-	(350)
Warrant liabilities fair value adjustment	(1,296)	(4,768)
Derivative liabilities fair value adjustment	90	(700)
Total other expense (income)	1,982	(5,477)
Loss before taxes	\$ (3,576)	\$ (7,002)
Income tax expense	1,100	-
Net loss	\$ (4,676)	\$ (7,002)
Net loss per share attributable to common stockholders - basic		
Net loss per share - basic	\$ (0.18)	\$ (0.72)
Net loss per share attributable to common stockholders - diluted		
Net loss per share - diluted	\$ (0.23)	\$ (0.72)
Weighted average common shares outstanding - basic and diluted		
Basic	25,802,700	9,744,577
Diluted	26,523,920	9,744,577

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

	<u>March 31, 2021</u>	<u>December 31, 2020</u>
Cash and cash equivalents	\$ 92,011	\$ 93,041
Total current assets	95,376	98,206
Operating lease right-of-use asset	2,950	2,999
Total assets	100,072	102,536
Warrant liabilities, current	16,225	17,564
Total current liabilities	24,932	26,396
Warrant liabilities, long term	33,635	33,592

Convertible debt and derivative liability		12,226		16,516
Operating lease liability, long term		3,215		3,274
Total liabilities		74,148		79,778
Total stockholders' equity		25,924		22,758
Total liabilities and stockholders' equity	\$	100,072	\$	102,536



Source: Scynexis