

August 16, 2021



# SCYNEXIS Reports Second Quarter 2021 Financial Results and Provides Corporate Update

- *BREXAFEMME<sup>®</sup> (ibrexafungerp tablets), the first novel antifungal class drug approved by the U.S. Food and Drug Administration (FDA) in more than 20 years, qualifies for 10 years of regulatory exclusivity and has 14 years of U.S. patent protection*
- *U.S. commercial launch of BREXAFEMME began in August; the treatment is now available at pharmacies and payer discussions are rapidly progressing*
- *Clinical development of ibrexafungerp continues to progress with the completion of enrollment in the Phase 3 CANDLE study in recurrent vulvovaginal candidiasis and ongoing Phase 1 dosing of a liposomal IV formulation*
- *Further strengthened balance sheet and projected cash runway into 2023 by accessing a \$10 million tranche of Hercules/SVB debt that became available following BREXAFEMME FDA approval*

JERSEY CITY, N.J., Aug. 16, 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 second quarter ended on June 30, 2021 and provided an update on recent clinical and corporate developments.

“We are not slowing down after our June 1, 2021 approval of BREXAFEMME, the first FDA-approved indication from our ibrexafungerp franchise,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “Our commercial team has been deployed to the field to call on their healthcare provider (HCP) customers to communicate the differentiating features and benefits of BREXAFEMME. We also continue to engage in an active dialogue with payers to establish coverage. While it is still too early to assess external demand for BREXAFEMME, I am extremely proud of our team for their strong execution which we believe will translate to more tangible results to drive shareholder value in the next quarter. In addition, our clinical development team remains focused on advancing ibrexafungerp for life-threatening invasive fungal infections in the hospital setting, including work on the new intravenous (IV) formulation currently in Phase 1.”

## **BREXAFEMME Commercial Update**

- **BREXAFEMME<sup>®</sup> (ibrexafungerp tablets) is now FDA-approved.** On June 1, 2021 the New Drug Application (NDA) for BREXAFEMME was approved by the FDA, becoming the first drug from a novel antifungal class (triterpenoid) in more than 20 years. BREXAFEMME was also granted a five-year exclusivity extension under the

GAIN Act for a total of 10 years of regulatory exclusivity and is also protected by a composition-of-matter patent until 2035.

- **BREXAFEMME launch update.** On June 29, 2021 SCYNEXIS hosted a virtual investor event to outline plans for the commercial launch of BREXAFEMME which began in August. BREXAFEMME is now available at pharmacies and the entire SCYNEXIS sales team is in the field actively engaging HCPs. An Early Experience Program was successfully implemented with key HCPs in July, confirming the need for a new treatment option and their willingness to prescribe BREXAFEMME. The Pharmacy and Therapeutic (P&T) review process with payers continues to rapidly progress with numerous P&T meetings already scheduled.

### **Ibrexafungerp Clinical Update**

- **Enrollment is complete in the Phase 3 CANDLE study, investigating the efficacy and safety of oral ibrexafungerp for the prevention of recurrent vulvovaginal candidiasis (VVC), for which there is no approved therapy in the U.S.** SCYNEXIS expects 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 with a potential approval in late 2022.
- **Dosing is ongoing in Phase 1 testing of the liposomal IV formulation of ibrexafungerp.** Based on promising pre-clinical data of the company'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 began in March 2021.
- **Ibrexafungerp Phase 3 data were presented at a key medical conference, reporting efficacy in non-*albicans* *Candida* (NAC) and patients with severe vulvovaginal candidiasis infections.** On April 30, 2021 SCYNEXIS presented posters on two data sets from SCYNEXIS' 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's strong activity in treating patients with NAC, which was comparable to that of the total patient population enrolled in the trial. Additionally, ibrexafungerp showed activity in patients with severe VVC, and may provide a treatment alternative where currently available therapies may not be satisfactory.
- **Key findings from interim data analyses of SCYNEXIS's ongoing refractory invasive fungal infections (rIFI) program, which is comprised of two open-label Phase 3 studies (FURI and CARES), were presented at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID).** On July 12, 2021 presentations examining positive data from the third interim analysis of the FURI study and first interim analysis of the CARES study, showed oral ibrexafungerp's ability to treat severe fungal infections in the hospital setting. An analysis by an independent data review committee of 33 patients from the Phase 3 FURI study evaluating

ibrexafungerp for the treatment of patients with refractory fungal disease found that 23 patients (70%) achieved clinical improvement, defined as complete or partial response. Seven patients (21%) maintained stable disease and 0 patients (0%) progressed. Three patients (9%) were considered as indeterminate. The first interim analysis of the 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 eight out of 10 patients (80%) 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.

## Corporate Developments

- In May 2021, SCYNEXIS entered into an agreement with a third party to sell a portion of its unused New Jersey Net Operating Loss (NOL) and research and development credits for approximately \$4.1 million.
- In May 2021, SCYNEXIS entered into a Loan Agreement with Hercules Capital, Inc. and Silicon Valley Bank for an aggregate principal amount of \$60 million. Under the terms of the Loan Agreement, SCYNEXIS received an initial tranche of \$20 million from the lenders on the closing date and received an additional \$10 million upon FDA approval of ibrexafungerp for the treatment of vaginal yeast infections. Subsequent cash injections will be available upon achieving certain milestones.
- In May 2021, SCYNEXIS announced the appointment of Christine Coyne as Chief Commercial Officer. She brings to the team deep anti-infective commercial expertise across hospital and community settings.

## Second Quarter 2021 Financial Results

Cash and cash equivalents totaled \$112.4 million on June 30, 2021, compared to \$93.0 million in cash, and cash equivalents on December 31, 2020. Based upon its existing operating plan, the company believes that its existing cash and cash equivalents, the sale of a portion of its New Jersey NOLs, and the anticipated sales of BREXAFEMME will enable SCYNEXIS to fund its operating requirements into 2023.

Research and Development expense for the three months ended June 30, 2021 decreased to \$4.7 million from \$8.5 million for the three months ended June 30, 2020. The decrease of \$3.8 million, or 44%, for the three months ended June 30, 2021, was primarily driven by a decrease of \$1.5 million in chemistry, manufacturing, and controls (CMC) expense, a decrease of \$1.4 million in clinical development expense, a decrease of \$0.3 million in preclinical expense, a decrease of \$0.2 million in regulatory expense, and a net decrease in other research and development expense of \$0.4 million.

Selling, General & Administrative expense for the three months ended June 30, 2021 increased to \$12.8 million from \$3.4 million for the three months ended June 30, 2020. The increase of \$9.4 million, or 281%, for the three months ended June 30, 2021 was primarily driven by a \$5.8 million increase in commercial related expense associated with the ongoing commercialization of BREXAFEMME, an increase of \$1.1 million in salary related costs, an increase of \$1.0 million in medical affairs expense, an increase of \$0.8 million in expense associated with increased information technology costs, and a net increase of \$0.7 million in

other selling, general and administrative expense.

Total other income was \$15.0 million for the three months ended June 30, 2021, compared to total other income of \$2.3 million for the three months ended June 30, 2020. During the three months ended June 30, 2021 and 2020, SCYNEXIS recognized non-cash gain of \$15.3 million and \$3.6 million, respectively, on the fair value adjustment of the warrant liabilities and during the three months ended June 30, 2021 and 2020, recognized non-cash gains of \$0.5 million and \$0.7 million on the fair value adjustment of the derivative liabilities, respectively.

Net income for the three months ended June 30, 2021 was \$1.7 million, or \$0.06 per basic and (\$0.22) per diluted share, compared to a net loss of \$6.4 million, or (\$0.64) per basic and diluted share for the three months ended June 30, 2020.

### **About Ibrexafungerp**

Ibrexafungerp [pronounced eye-BREX-ah-FUN-jerp] is an 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 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 New Drug Application (NDA) for BREXAFEMME<sup>®</sup> (ibrexafungerp tablets) was approved by the U.S. Food and Drug Administration (FDA) on June 1, 2021. FDA 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. We are developing our lead asset, ibrexafungerp (formerly known as SCY-078), as a broad-spectrum, systemic antifungal for multiple fungal indications in both the community and hospital settings. The New Drug Application (NDA) for BREXAFEMME<sup>®</sup> (ibrexafungerp tablets) was approved by the U.S. Food and Drug Administration (FDA) on June 1, 2021. For more information, visit [www.brexafemme.com](http://www.brexafemme.com). We are also continuing late-stage clinical development of ibrexafungerp for the prevention of recurrent VVC as well as the treatment of life-threatening invasive fungal infections in hospitalized patients. For more information, visit [www.scynexis.com](http://www.scynexis.com).

### **Forward-Looking Statements**

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's belief that its execution against internal targets will translate to more tangible results to drive shareholder

value in the next quarter, SCYNEXIS's expected revenues from BREXAFEMME for Vulvovaginal Candidiasis, SCYNEXIS's expectations for the Phase 3 CANDLE study with respect to the timing for 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 and advancing ibrexafungerp for life-threatening invasive fungal infections in the hospital setting, including work on the new IV formulation currently in Phase 1. 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: BREXAFEMME may not be accepted by physicians and patients at the rate SCYNEXIS expects; risks inherent in SCYNEXIS' ability to successfully develop and obtain FDA approval for ibrexafungerp for additional indications, including the IV formulation of ibrexafungerp currently in Phase 1; 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 and commercialize its products. 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](mailto:ikoffler@lifesciadvisors.com)

**Media Relations**

Gloria Gasaatura

LifeSci Communications

Tel: (646) 970-4688

[ggasaatura@lifescicomms.com](mailto:ggasaatura@lifescicomms.com)

**SCYNEXIS, INC.**

**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except share and per share data)

	<b>Three Months Ended June</b>	
	<b>30,</b>	
	<b>2021</b>	<b>2020</b>
	<hr/>	<hr/>
Revenue	\$ -	\$ -

Operating expenses:		
Research and development	4,734	8,469
Selling, general and administrative	12,774	3,357
Total operating expenses	<u>17,508</u>	<u>11,826</u>
Loss from operations:	(17,508)	(11,826)
Other expense (income):		
Loss on extinguishment of debt	-	806
Amortization of debt issuance costs and discount	269	321
Interest income	(6)	(36)
Interest expense	445	319
Other income	(3)	(60)
Other expense	-	602
Warrant liabilities fair value adjustment	(15,271)	(3,560)
Derivative liabilities fair value adjustment	<u>(462)</u>	<u>(693)</u>
Total other income	<u>(15,028)</u>	<u>(2,301)</u>
<b>Loss before taxes</b>	<u>\$ (2,480)</u>	<u>\$ (9,525)</u>
Income tax benefit	<u>(4,138)</u>	<u>(3,144)</u>
<b>Net income (loss)</b>	<u>\$ 1,658</u>	<u>\$ (6,381)</u>

Net income (loss) per share attributable to common stockholders - basic		
Net income (loss) per share - basic	\$ 0.06	\$ (0.64)
Net loss per share attributable to common stockholders - diluted		
Net loss per share - diluted	\$ (0.22)	\$ (0.64)
Weighted average common shares outstanding - basic and diluted		
Basic	26,015,292	10,009,614
Diluted	26,487,973	10,009,614

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

	<u>June 30,</u> <u>2021</u>	<u>December</u> <u>31, 2020</u>
Cash and cash equivalents	\$ 112,445	\$ 93,041
Total current assets	115,631	98,206
Operating lease right-of-use asset	2,899	2,999
Total assets	121,131	102,536
Warrant liabilities, current	10,499	17,564
Total current liabilities	19,879	26,396

Warrant liabilities, long term	24,452	33,592
Convertible debt and derivative liability	11,996	16,516
Operating lease liability, long term	3,270	3,274
Total liabilities	88,811	79,778
Total stockholders' equity	32,320	22,758
Total liabilities and stockholders' equity	\$ 121,131	\$ 102,536



Source: Scynexis