

November 13, 2023



SCYNEXIS Reports Third Quarter 2023 Financial Results and Provides Corporate Update

- IND enabling development activities for SCY-247, the next generation fungerp from SCYNEXIS' proprietary antifungal platform, continue to advance
- Remediation strategies following the voluntary recall of BREXAFEMME® and the MARIO study clinical hold are being evaluated
- With cash, cash equivalents and investments of \$105.2 million as of September 30, 2023, SCYNEXIS projects a cash runway of more than two years

JERSEY CITY, N.J., Nov. 13, 2023 (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 third quarter ended September 30, 2023.

"We faced unexpected challenges associated with the recent BREXAFEMME® recall and the clinical hold placed on the MARIO trial this quarter," said David Angulo, M.D., President and Chief Executive Officer of SCYNEXIS. "While options for resolution of these issues are being evaluated we continue making progress towards data analysis for recently completed clinical studies (FURI, CARES, SCYNERGIA and VANQUISH). Our solid cash position has allowed us to advance the development of our next generation triterpenoid antifungal 'SCY-247' and continue to seek to maximize shareholder value while avoiding the volatile capital markets."

Ibrexafungerp Clinical and Regulatory Updates

- As previously announced, SCYNEXIS entered into an exclusive license agreement with GSK plc (LSE/NYSE: GSK) to commercialize BREXAFEMME® (ibrexafungerp tablets) for vulvovaginal candidiasis (VVC) and develop ibrexafungerp for invasive and life-threatening fungal diseases. Under the agreement, SCYNEXIS has received the \$90 million upfront payment as well as the first development milestone of \$25 million.
- SCYNEXIS became aware that a non-antibacterial beta-lactam drug substance was manufactured using equipment common to the manufacturing process for ibrexafungerp. Current FDA draft guidance recommends segregating the manufacture of non-antibacterial beta-lactam compounds from other compounds. It is not known whether any ibrexafungerp has been contaminated with a beta-lactam compound. Nonetheless, in light of this risk and out of an abundance of caution, a voluntary recall of BREXAFEMME® (ibrexafungerp tablets) due to potential cross contamination with a non-antibacterial beta-lactam was initiated. The Phase III MARIO study was also placed on hold due to this potential cross-contamination.
- Data analysis for completed studies (FURI, CARES, SCYNERGIA and VANQUISH) is

ongoing and not affected by the clinical hold.

- SCYNEXIS and partner Hansoh Pharmaceutical Group Company Limited (3692.HK) announced that China's NMPA has accepted for review a New Drug Application (NDA) for oral ibrexafungerp tablets for the treatment of adult and post-menarchal pediatric females with VVC in the Chinese mainland. The application, submitted by Hansoh Pharma, is based on positive results from Phase 3 studies in which ibrexafungerp successfully achieved statistically significant superiority over placebo for the primary and key secondary study endpoints.

Scientific Presentations and Publications

- Presented new preclinical data on second generation fungerp SCY-247 at the 11th Congress on Trends in Medical Mycology (TIMM) held in Athens, Greece October 20-23, 2023. The oral presentation featured a preclinical study that demonstrated potent and broad-spectrum activity of SCY-247 against a range of fungal pathogens, including multi-drug resistant strains, in *in vitro* and *in vivo* models. Physician awareness and enthusiasm towards the fungerp class addressing critical antimicrobial resistant threats continues to build at medical conferences.

SCY-247 Preclinical Development Program

- IND-enabling development activities for SCY-247, the next generation fungerp from SCYNEXIS' proprietary antifungal platform, continue to progress. A portion of these activities, including assessing the activity against *Candida auris* and Mucorales, are being supported by NIH grants. IND filing for this compound is anticipated in the second half of 2024.

Third Quarter 2023 Financial Results

SCYNEXIS recognized a loss of (\$0.6) million in product revenue for Q3 2023 compared with product revenue of \$1.6 million in Q3 2022. The (\$0.6) million loss in product revenue for Q3 2023 was primarily due to a \$3.5 million reserve recognized for the product recall in September 2023. The Company ceased all promotion of BREXAFEMME® in Q4 2022.

Research and development expense for Q3 2023 was \$6.5 million, compared to \$6.4 million for Q3 2022.

Selling, general & administrative (SG&A) expense for Q3 2023 decreased to \$5.0 million from \$16.7 million for Q3 2022. The decrease was primarily driven by decreased commercial costs and salary expense associated with BREXAFEMME® commercialization.

Total other income was \$8.3 million for Q3 2023, versus total other expense of \$7.8 million for Q3 2022. During Q3 2023 and Q3 2022, SCYNEXIS recognized a non-cash gain of \$7.5 million and a non-cash loss of \$6.5 million, respectively, on the fair value adjustment of the warrant liabilities.

Net loss for Q3 2023 was \$1.8 million, or \$0.04 basic loss per share compared to a net loss of \$29.6 million, or \$0.62 basic loss per share for Q3 2022.

Cash Balance

Cash, cash equivalents and investments totaled \$105.2 million on September 30, 2023, compared to \$73.5 million on December 31, 2022. Based upon the company's current operating plan, SCYNEXIS believes that its existing cash, cash equivalents and investments provides a cash runway beyond two years.

SCYNEXIS filed a shelf registration statement with the Securities and Exchange Commission today to replace its current shelf registration statement, which will be expiring in December 2023, as well as a registration statement for the issuance of shares pursuant to outstanding warrants as a result of expiring or expired shelf registration statements for the issuance of those shares.

About Triterpenoid Antifungals

Triterpenoid antifungals (also known as "fungerp") are a novel class of structurally-distinct glucan synthase inhibitors that combine the well-established activity of glucan synthase inhibitors with the potential flexibility of having oral and intravenous (IV) formulations. They have demonstrated broad-spectrum antifungal activity against multidrug-resistant pathogens, including azole- and echinocandin-resistant strains. Ibrexafungerp is the first representative of this novel class of antifungal agents. Ibrexafungerp, formerly known as SCY-078, is currently approved in the U.S. for the treatment of vulvovaginal candidiasis and is in late-stage of development for invasive candidiasis and other indications. SCY-247 is a next generation fungerp in pre-clinical development for the treatment of life-threatening and often multi-drug resistant fungal diseases including *Candida auris* infections.

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. SCYNEXIS is developing its proprietary triterpenoid antifungal compounds as broad-spectrum, systemic, antifungal agents for multiple fungal indications. The U.S. Food and Drug Administration (FDA) approved the first representative of this antifungal class BREXAFEMME® (ibrexafungerp tablets) in June 2021, for its first indication in vulvovaginal candidiasis (VVC), followed by a second indication in November 2022, for reduction in the incidence of recurrent VVC. Late-stage clinical investigation of ibrexafungerp for the treatment of life-threatening invasive fungal infections is ongoing. Additional assets in the novel "fungerp" class of antifungals are currently in the pre-clinical and discovery phase, including the compound SCY-247. For more information, visit 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 expectation that it will have a cash runway of more than two years. 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 regulatory and other costs in developing 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 filed

on March 31, 2023, and form 10-Q for the quarter ending September 30th, 2023, including under the caption "Risk Factors." 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.

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 44,071	\$ 45,814
Short-term investments	44,001	27,689
Prepaid expenses and other current assets	3,172	2,503
License agreement receivable	2,349	—
License agreement contract asset	19,309	—
Accounts receivable, net	2,245	2,101
Inventory, net	13,114	899
Restricted cash	380	55
Total current assets	128,641	79,061
Investments	17,115	—
Other assets	25	5,511
Deferred offering costs	73	73
Restricted cash	164	163
Intangible assets, net	103	408
Operating lease right-of-use asset (See Note 8)	2,425	2,594
Total assets	\$ 148,546	\$ 87,810
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,490	\$ 5,937
Accrued expenses	9,543	5,628
Deferred revenue, current portion	2,435	—
Other liabilities, current portion (See Note 7)	—	5,771
Operating lease liability, current portion (See Note 8)	325	282
Warrant liabilities	997	—

Total current liabilities	16,790	17,618
Deferred revenue	1,646	—
Warrant liabilities	23,638	18,644
Convertible debt and derivative liability (See Note 7)	11,808	11,001
Loan payable	—	34,393
Operating lease liability (See Note 8)	2,673	2,921
Total liabilities	56,555	84,577
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value, authorized 5,000,000 shares as of September 30, 2023 and December 31, 2022; 0 shares issued and outstanding as of September 30, 2023 and December 31, 2022	—	—
Common stock, \$0.001 par value, 150,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 37,175,815 and 32,682,342 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	40	36
Additional paid-in capital	427,612	425,485
Accumulated deficit	(335,661)	(422,288)
Total stockholders' equity	91,991	3,233
Total liabilities and stockholders' equity	\$ 148,546	\$ 87,810

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

	Three Months Ended September 30,	
	2023	2022
Revenue:		
Product (loss) revenue, net	\$ (614)	\$ 1,557
License agreement revenue	2,375	—
Total revenue	1,761	1,557
Operating expenses:		
Cost of product revenue	379	189
Research and development	6,466	6,430
Selling, general and administrative	5,014	16,739
Total operating expenses	11,859	23,358
(Loss) income from operations	(10,098)	(21,801)
Other (income) expense:		

Amortization of debt issuance costs and discount	360	396
Interest income	(1,263)	(531)
Interest expense	212	1,379
Warrant liabilities fair value adjustment	(7,468)	6,497
Derivative liabilities fair value adjustment	(182)	42
Total other (income) expense	<u>(8,341)</u>	<u>7,783</u>
(Loss) income before taxes	(1,757)	(29,584)
Income tax benefit	<u>—</u>	<u>—</u>
Net (loss) income	\$ (1,757)	\$ (29,584)
Net (loss) income per share attributable to common stockholders – basic		
Net (loss) income per share – basic	\$ (0.04)	\$ (0.62)
Net (loss) income per share attributable to common stockholders – diluted		
Net (loss) income per share – diluted	\$ (0.04)	\$ (0.62)
Weighted average common shares outstanding – basic and diluted		
Basic	<u>47,891,996</u>	<u>47,503,821</u>
Diluted	<u>47,891,996</u>	<u>47,503,821</u>



Source: Scynexis