

# SCYNEXIS Reports Third Quarter 2024 Financial Results and Provides Corporate Update

- Clinical study reports for the FURI, CARES and NATURE trials in refractory or resistant invasive fungal infections were delivered to GSK, triggering a \$10 million development milestone payment to SCYNEXIS, received in Q3 2024.
- SCY-247 preclinical studies were presented at medical conferences and continue to show potent and broad antifungal activity. Phase 1 study initiation is anticipated in Q4 2024.
- SCYNEXIS ended Q3 2024 with cash, cash equivalents and investments of \$84.9 million, including the recently earned \$10.0 million development milestone, and projects a cash runway into Q3 2026.
- SCYNEXIS will attend Guggenheim's Inaugural Global Healthcare Conference in Boston on November 12<sup>th</sup> and hold one-on-one meetings with investors.

JERSEY CITY, N.J., Nov. 06, 2024 (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, 2024.

"We see substantial value in our ibrexafungerp partnered programs and have been making significant progress advancing the manufacturing of clinical trial materials, which would enable the re-start of the Phase 3 MARIO trial in invasive candidiasis, anticipated in early 2025." said David Angulo, M.D., President and Chief Executive Officer. "Additionally, SCY-247 has demonstrated highly encouraging preclinical results in a broad range of invasive fungal infections, underscoring its potential to be a new therapeutic to fight hard-to-treat fungal pathogens. We continue to share these promising results with the scientific community, most recently at IDWeek 2024. A planned Phase 1 trial of SCY-247 remains on track to initiate in the fourth quarter of 2024. We are also pleased to have completed the FURI, CARES and NATURE studies of ibrexafungerp in refractory invasive fungal infections, which showed positive results consistent with results reported from previous interim analyses. Delivery of final study reports to our partner triggered a \$10 million milestone payment received in the third quarter."

### **SCY-247 Preclinical Development Program**

 Preclinical data from studies of SCY-247, the second generation fungerp from SCYNEXIS' proprietary antifungal platform, were presented at multiple medical meetings, including the <u>Mycoses Study Group Education & Research Consortium</u> (MSGERC) Biennial Meeting in September 2024 and IDWeek in October 2024. These presentations highlighted encouraging preclinical efficacy and pharmacokinetic data on SCY-247 in multiple models of invasive fungal infections, including:

- Positive dose-dependent efficacy against Candida albicans mouse model following oral administration;
- Significant and dose-dependent reductions in kidney and lung fungal burden in *Candida glabrata* mouse model;
- Prolonged survival and reductions in lung and brain fungal burden in a pulmonary mucormycosis mouse model; and
- High tissue distribution into organs of concern for invasive fungal infections.
- Phase I initiation continues to be anticipated in Q4 2024.

# **Ibrexafungerp Clinical Updates**

- Final study reports from the completed FURI, CARES and NATURE studies were
  delivered to partner, GSK in July 2024. Delivery of these reports triggered a \$10 million
  development milestone payment to SCYNEXIS which was received in the third quarter
  of 2024. Results from the FURI and CARES studies are planned to be presented by
  GSK at a future medical meeting. For more information on the trials, please visit
  ClinicalTrials.gov (CARES: <a href="NCT03363841">NCT03363841</a>; FURI: <a href="NCT03059992">NCT03059992</a>).
- Third-party manufacturing of new batches of ibrexafungerp for use in clinical trials is in progress, and SCYNEXIS anticipates restarting the Phase 3 MARIO study in invasive candidiasis in Q1 2025.

#### **Guggenheim Conference Participation**

Scynexis management will be participating in the Guggenheim Securities Healthcare Conference, taking place in Boston from November 11-13, 2024. Please contact your Guggenheim representative to schedule a meeting with the team.

**Date:** November 12, 2024 **Format:** 1x1 Meetings

#### Third Quarter 2024 Financial Results

For the three months ended September 30, 2024 and 2023, revenue primarily consists of \$0.7 million and \$2.4 million, respectively, in license agreement revenue associated with the GSK license agreement.

Research and development expense for the three months ended September 30, 2024 was \$8.1 million compared to \$6.5 million for the same period in 2023. The increase of \$1.6 million, or 25%, for the three months ended September 30, 2024, was primarily driven by an increase of \$2.2 million in chemistry, manufacturing, and controls (CMC) expense, an increase of \$0.9 million in preclinical expense, and a net increase in other research and development expense of \$0.4 million, offset in part by a decrease of \$1.6 million in clinical expense and a decrease of \$0.3 million in salaries primarily associated with medical affairs.

SG&A expense for the three months ended September 30, 2024 decreased to \$2.9 million from \$5.0 million for the same period in 2023. The decrease of \$2.1 million, or 42%, for the

three months ended September 30, 2024, was primarily driven by a decrease of \$1.5 million in professional fees and a decrease of \$0.5 million in commercial expense due to the costs incurred in the prior period associated with BREXAFEMME.

Total other income was \$7.1 million for the three months ended September 30, 2024, versus total other income of \$8.3 million for the same period in 2023. The variance is mainly due to the fair value adjustment related to the warrant liabilities. For the three months ended September 30, 2024 and 2023, we recognized gains of \$6.8 million and \$7.5 million, respectively, on the fair value adjustment for warrant liabilities primarily due to the changes in our stock price during the periods.

Net loss for the three months ended September 30, 2024, was \$2.8 million, or \$0.06 basic loss per share, compared to a net loss of \$1.8 million, or \$0.04 basic loss per share for the same period in 2023.

#### **Cash Balance**

Cash, cash equivalents and investments totaled \$84.9 million on September 30, 2024, compared to \$98.0 million on December 31, 2023. Based upon the company's current operating plan, SCYNEXIS believes that its existing cash, cash equivalents and investments provide a cash runway into Q3 2026.

## **About Triterpenoid Antifungals**

Triterpenoid antifungals (also known as "fungerps") 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 the company's proprietary antifungal platform "fungerps." Ibrexafungerp, the first representative of this novel class, has been licensed to GSK. The U.S. Food and Drug Administration (FDA) approved BREXAFEMME<sup>®</sup> (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 in hospitalized patients is ongoing. Additional antifungal assets from this novel class are currently in 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 into Q3 2026; anticipated initiation of Phase 1 clinical studies of SCY-247 in Q4 of 2024; and the anticipated resumption of the Phase 3 MARIO study. 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 28, 2024, and form 10-Q for the quarter ending September 30, 2024, 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.

### **CONTACT:**

**Investor Relations** 

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

	 Three Months Ended September 30,		
	2024		2023
Revenue:			
Product (loss) revenue, net	\$ _	\$	(614)
License agreement revenue	 660		2,375
Total revenue	660		1,761
Operating expenses:			
Cost of product revenue	_		379
Research and development	8,073		6,466
Selling, general and administrative	2,907		5,014
Total operating expenses	 10,980		11,859
Loss from operations	(10,320)		(10,098)
Other (income) expense:			
Amortization of debt issuance costs and discount	441		360
Interest income	(1,020)		(1,263)
Interest expense	213		212

Warrant liabilities fair value adjustment		(6,751)	(7,468)	
Derivative liabilities fair value adjustment		_	(182)	
Total other income		(7,117)	(8,341)	
Loss before taxes		(3,203)	(1,757)	
Income tax benefit		(395)	<u> </u>	
Net loss	\$	(2,808)	\$ (1,757)	
Net loss per share attributable to common stockholders –				
basic				
Net loss per share – basic	\$	(0.06)	\$ (0.04)	
Net loss per share attributable to common stockholders –				
diluted				
Net loss per share – diluted	\$	(0.06)	\$ (0.04)	
Weighted average common shares outstanding – basic and				
diluted				
Basic	48,	618,693	47,891,996	
Diluted	48,	618,693	47,891,996	

# SCYNEXIS, INC. UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands, except share and per share data)

	September 3 2024		, December 31, 2023	
Assets				
Current assets:				
Cash and cash equivalents	\$	28,730	\$	34,050
Short-term investments		40,098		40,312
Prepaid expenses and other current assets		1,538		5,548
License agreement receivable		153		2,463
License agreement contract asset		9,509		19,363
Restricted cash		435		380
Total current assets		80,463		102,116
Investments		16,116		23,594
Deferred offering costs		187		175
Restricted cash		109		163
Operating lease right-of-use asset		2,163		2,364
Total assets	\$	99,038	\$	128,412
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Liabilities and stockholders' equity

Current liabilities:

Accounts payable	\$ 4,955	\$ 7,149
Accrued expenses	5,508	7,495
Deferred revenue, current portion	1,642	1,189
Operating lease liability, current portion	389	340
Warrant liabilities		130
Convertible debt and derivative liability	13,225	
Total current liabilities	25,719	16,303
Deferred revenue	1,294	 2,727
Warrant liabilities	11,212	21,680
Convertible debt and derivative liability	_	12,159
Operating lease liability	2,284	2,581
Total liabilities	40,509	55,450
Commitments and contingencies Stockholders' equity: Preferred stock, \$0.001 par value, authorized 5,000,000 shares as of September 30, 2024 and December 31, 2023; 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023 Common stock, \$0.001 par value, 150,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 37,943,241 and 37,207,799 shares issued and outstanding as of September 30, 2024 and December 31,		
2023, respectively	41	40
Additional paid-in capital	430,590	428,169
Accumulated deficit	(372,102)	(355,247)
Total stockholders' equity	 58,529	 72,962
Total liabilities and stockholders' equity	\$ 99,038	\$ 128,412



Source: Scynexis