

# SCYNEXIS Reports Second Quarter 2023 Financial Results and Provides Corporate Update

- SCYNEXIS reported the closing of an exclusive license agreement with GSK for BREXAFEMME<sup>®</sup> (Ibrexafungerp Tablets). SCYNEXIS received an upfront payment of \$90 million upon deal close.
- SCYNEXIS announced the achievement of the first development milestone of \$25 million under the exclusive license agreement with GSK, based on the progression of the Phase 3 MARIO trial of ibrexafungerp in invasive candidiasis.
- SCYNEXIS and partner Hansoh Pharma announced the acceptance of a New Drug Application (NDA) by China's National Medical Products Administration (NMPA) for oral ibrexafungerp tablets for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis in the Chinese mainland.
- IND enabling development for SCY-247, the next generation fungerp, continues to advance.
- With cash, cash equivalents and investments of \$91.9 million as of June 30, 2023, and future receipt of the \$25 million development milestone from GSK, SCYNEXIS anticipates modest near-term spending and a projected cash runway beyond two years.

JERSEY CITY, N.J., Aug. 14, 2023 (GLOBE NEWSWIRE) -- SCYNEXIS, Inc. (NASDAQ: <u>SCYX</u>), 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 June 30, 2023.

"In the second quarter, we continued to execute on our key priorities, by maximizing ibrexafungerp's value and by advancing our ground-breaking class of antifungals to fight serious global health threats," said David Angulo, M.D., President and Chief Executive Officer of SCYNEXIS. "We were pleased to achieve the first development milestone under our exclusive licensing agreement with GSK based on the progress of the Phase 3 ibrexafeungerp MARIO study and to report the successful NDA filing of ibrexafungerp for VVC in China. Our innovative triterpenoid antifungal platform is poised to provide significant value and we are rapidly advancing the next generation fungerp SCY-247 and anticipate filing an IND in 2024. With our current cash balance and modest projected spending over the next years, we are well-positioned to support the entire clinical development of SCY-247 and continue the fight against life-threatening fungal infections."

## **Corporate Developments**

 On June 21, 2023, SCYNEXIS announced the achievement of a \$25 million performance-based development milestone under its exclusive license agreement with GSK for ibrexafungerp. The milestone payment follows the achievement of a development goal for the Phase 3 MARIO study for ibrexafungerp in invasive candidiasis.

# **Ibrexafungerp Clinical and Regulatory Updates**

SCYNEXIS and partner Hansoh Pharmaceutical Group Company Limited (3692.HK) announced that China's NMPA has accepted for review an NDA for oral ibrexafungerp tablets for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (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.

### **Ibrexafungerp Scientific Presentations and Publications**

Presented an overview of the innovative study design of the ongoing Phase 3 MARIO trial investigating oral ibrexafungerp as a step-down therapy for invasive candidiasis and shared interim data analyses from its ongoing Phase 3 FURI and CARES studies at the 33rd Annual European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) held in Copenhagen, Denmark, April 15-18, 2023.

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

IND-enabling development activities for SCY-247 continue to progress. SCY-247 is a
broad-spectrum antifungal with potential oral and IV systemic therapeutic formulations
for multiple drug-resistant pathogens. 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.

### Second Quarter 2023 Financial Results

We recognized \$131.5 million in total revenue for Q2 2023 compared with \$1.3 million in Q2 2022. The increase in revenue was associated primarily with the recognition of \$131.0 million in licensing agreement revenues from GSK.

Research and development expense for Q2 2023 was \$7.0 million, compared to \$7.1 million for Q2 2022.

Selling, general & administrative (SG&A) expense for Q2 2023 decreased to \$7.5 million from \$15.8 million for Q2 2022. The decrease of \$8.3 million, or 53%, for Q2 2023, was primarily driven by a decrease of \$9.0 million in commercial expense due to the costs incurred in the prior comparable period associated with the active promotion of BREXAFEMME which ceased in the fourth quarter of 2022, a decrease of \$1.1 million in salary related expense primarily driven by the workforce reduction in the fourth quarter of 2022 concentrated in the commercial and medical affairs functions, a decrease of \$0.5 million in other medical affairs related expense, and a net decrease in other selling, general, and administrative expense of \$0.6 million, offset in part by an increase in professional fees of \$2.9 million. The \$2.9 million increase in professional fees is primarily due to a \$3.1 million expense incurred during the current period for business development associated with the License Agreement with GSK.

Total other income was \$5.7 million for Q2 2023, versus total other income of \$8.4 million for Q2 2022. During Q2 2023 and Q2 2022, SCYNEXIS recognized a non-cash gain of \$8.2 million and a non-cash gain of \$9.7 million, respectively, on the fair value adjustment of the warrant liabilities.

Net income for Q2 2023 was \$122.3 million, or \$2.56 basic income per share and \$2.46 diluted income per share, compared to a net loss of \$13.3 million, or \$0.31 basic and diluted loss per share for Q2 2022.

### Cash Balance

Cash, cash equivalents and investments totaled \$91.9 million on June 30, 2023, compared to \$73.5 million on December 31, 2022, The June 30, 2023 cash balance is after deduction of the approximately \$36 million Hercules Capital and Silicon Valley Bridge Bank loan which was repaid in full in the second quarter and does not include the \$25 million development milestone recognized in the second quarter. Based upon its current operating plan which assumes modest spending in 2024 and receipt of the \$25 million development milestone payment from partner GSK, SCYNEXIS believes that its existing cash, cash equivalents and investments will provide a cash runway beyond two years.

### **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 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<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 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 <a href="https://www.scynexis.com">www.scynexis.com</a>.

### 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, 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:**

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

	Three Months Ended June 30,				
		2023		2022	
Revenue:			,		
Product revenue, net	\$	468	\$	1,323	
License agreement revenue		130,986		_	
Total revenue		131,454	,	1,323	
Operating expenses:					
Cost of product revenue		426		144	
Research and development		7,040		7,131	
Selling, general and administrative		7,474		15,786	
Total operating expenses					
		14,940		23,061	
Income (loss) from operations		116,514		(21,738)	
Other (income) expense:					
Amortization of debt issuance costs and discount		1,998		421	
Interest income		(737)		(181)	
Interest expense		1,249		1,231	
Other income		_		_	
Warrant liabilities fair value adjustment		(8,214)		(9,682)	
Derivative liabilities fair value adjustment		(42)		(182)	

Total other (income) expense		(5,746)		(8,393)	
Income (loss) before taxes		122,260		(13,345)	
Income tax benefit		_		_	
Net income (loss)	\$	122,260	\$	(13,345)	
Net income (loss) per share attributable to common					
stockholders – basic					
Net income (loss) per share – basic	\$	2.56	\$	(0.31)	
Net income (loss) per share attributable to common					
stockholders – diluted					
Net income (loss) per share – diluted	\$	2.46	\$	(0.31)	
Weighted average common shares outstanding – basic					
and diluted					
Basic	47	47,837,393		43,285,232	
Diluted	49,923,361		43,285,232		

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

	June 30, 2023	De	December 31, 2022	
Assets		_		
Current assets:				
Cash and cash equivalents	\$ 57,905	\$	45,814	
Short-term investments	27,637	•	27,689	
Prepaid expenses and other current assets	2,669	1	2,503	
License agreement receivable	25,000	)	_	
License agreement contract asset	19,249	1		
Accounts receivable, net	2,345		2,101	
Inventory, net	10,290		899	
Restricted cash	435		55	
Total current assets	145,530		79,061	
Investments	6,336		<u> </u>	
Other assets	64		5,511	
Deferred offering costs	73	j	73	
Restricted cash	163	j	163	
Intangible assets, net	206	;	408	
Operating lease right-of-use asset (See Note 8)	2,484		2,594	
Total assets	\$ 154,856	\$	87,810	
Liabilities and stockholders' equity				

Current liabilities:			
Accounts payable	\$	3,416	\$ 5,937
Accrued expenses		7,190	5,628
Deferred revenue, current portion		3,229	
Other liabilities, current portion (See Note 7)		_	5,771
Operating lease liability, current portion (See Note 8)		310	282
Warrant liabilities		2,013	
Total current liabilities		16,158	17,618
Deferred revenue		1,140	
Warrant liabilities		30,090	18,644
Convertible debt and derivative liability (See Note 7)		11,630	11,001
Loan payable			34,393
Operating lease liability (See Note 8)		2,760	2,921
Total liabilities		61,778	84,577
Commitments and contingencies			_
Stockholders' equity:			
Preferred stock, \$0.001 par value, authorized 5,000,000 shares as of June 30, 2023 and December 31, 2022; 0 shares issued and outstanding as of June 30, 2023 and			
December 31, 2022			
Common stock, \$0.001 par value, 150,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 37,175,665 and 32,682,342 shares issued and outstanding			
as of June 30, 2023 and December 31, 2022, respectively		40	36
Additional paid-in capital	4	426,942	425,485
Accumulated deficit	(;	333,904)	 (422,288)
Total stockholders' equity		93,078	3,233
Total liabilities and stockholders' equity	\$	154,856	\$ 87,810



Source: Scynexis