March 31, 2023

SCYNEXIS Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

- SCYNEXIS announced it has signed an exclusive agreement with GSK to commercialize and further develop BREXAFEMME® (ibrexafungerp tablets) for all indications. GSK will make an upfront payment to SCYNEXIS of $90 million, as well as potential future milestones and tiered royalties.
- SCYNEXIS retains rights to all other assets in the novel “fungerp” antifungal class, including SCY-247, currently in preclinical investigation, with GSK having a right of first negotiation to these preclinical and discovery stage compounds.
- Enrollment is complete in the FURI and CARES Phase 3 trials of ibrexafungerp to fight serious drug-resistant refractory invasive fungal infections and in the SCYNERGIA Phase 2 trial of ibrexafungerp in invasive aspergillosis.
- SCYNEXIS ended Q4 2022 with cash, cash equivalents and short-term investments of $73.5 million, and upon closure of the GSK transaction and receipt of the upfront payment of $90 million, will have a projected cash runway of more than two years.

JERSEY CITY, N.J., March 31, 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 fourth quarter and full year ended on December 31, 2022.

“We are thrilled to partner with GSK, a leading global organization in the fight against infectious diseases, an area of increasing public health urgency,” said David Angulo, M.D., President and Chief Executive Officer of SCYNEXIS. “For SCYNEXIS and our shareholders, this deal is transformational and creates significant value, both strengthening our balance sheet and enhancing the opportunity to deliver additional innovative therapies to patients with unmet needs. We will continue advancing ibrexafungerp clinical programs and are in a strong financial position to execute our strategic priorities this year and beyond. With our good track record of efficiently bringing to market first-in-class compounds and the additional resources on hand, our organization is well positioned to continue developing groundbreaking therapies, including our next generation fungerp SCY-247.”

BREXAFEMME Commercial Updates

- **BREXAFEMME net sales were $1.4 million in Q4 2022 and $5.0 million in 2022.** According to IQVIA data, there were 5,125 total prescriptions for BREXAFEMME written in Q4 2022, and more than 20,000 total prescriptions written in 2022.
- **BREXAFEMME was prescribed by approximately 2,546 individual healthcare professionals** (HCPs) in Q4, an increase of 2% over Q3 2022, highlighting the

persistence of the prescriber base even in the absence of personal promotion.

Ibrexafungerp Clinical and Regulatory Updates

- **SCYNEXIS announced U.S. Food and Drug Administration (FDA) approval of a supplemental NDA for a second indication for BREXAFEMME for the reduction in incidence of recurrent vulvovaginal candidiasis (RVVC).** The approval was based on positive results from the pivotal Phase 3 CANDLE study reported in February 2022. BREXAFEMME is the first and only FDA-approved therapy for both the treatment of VVC and the reduction in the incidence of RVVC.
- **Enrollment continues for the MARIO trial, a global Phase 3 study to evaluate ibrexafungerp as an oral step-down treatment for invasive candidiasis (IC) in the hospital setting.** Additional sites are being opened globally.
- **Enrollment is complete in the FURI and CARES Phase 3 trials evaluating ibrexafungerp as salvage therapy in refractory invasive fungal infections, including candidiasis, aspergillosis and other severe fungal infections**.
- **SCYNEXIS received Innovation Passport Designation from the United Kingdom (U.K.) Medicines and Healthcare Products Regulatory Agency (MHRA) for ibrexafungerp for the treatment of IC.** The Innovation Passport is the first step and point of entry into the U.K.'s Innovative Licensing and Access Pathway (ILAP), designed to accelerate time to market and facilitate patient access to critical medicines. Innovation Passport designation is awarded to companies developing therapies that have the potential to provide significant benefits to patients with life-threatening or severely debilitating conditions where there is a significant patient or public health need.
- **Enrollment continues in VANQUISH, a Phase 3b, open-label, multicenter study to evaluate the efficacy, safety and tolerability of oral ibrexafungerp as a treatment for VVC in patients who have failed treatment with fluconazole, based on mycological and clinical outcomes.**
- **Enrollment is complete for the SCYNERGIA Phase 2 study evaluating the safety and efficacy of ibrexafungerp co-administered with voriconazole in patients with invasive pulmonary aspergillosis.**

Ibrexafungerp Scientific Presentations and Publications

- **Publication of an article in the *Journal of Fungi* in October 2022 highlighting the potential use of ibrexafungerp as a novel treatment option for invasive infections caused by opportunistic molds.** The article emphasizes ibrexafungerp's advantages versus available antifungal drugs, including its oral bioavailability and its broad-spectrum activity against various fungal pathogens, including azole-resistant *Aspergillus* species. Data from preclinical and clinical studies showcased in the article provide rationale for the continued development of ibrexafungerp as a potential treatment for invasive fungal and mold infections.
- **Peer-reviewed publication of positive results from a pooled analysis of two Phase 3 studies (VANISH-303 and VANISH-306) in the *Journal of Women's Health* in October 2022.** Clinical cure rates, in the pooled analysis, were statistically significantly greater for ibrexafungerp when compared with placebo ($p < 0.0001$). In the

pooled analysis, patients receiving ibrexafungerp experienced significantly higher rates of clinical improvement, complete symptom resolution, and mycological cure compared to placebo (all $p < 0.0001$). Ibrexafungerp demonstrated efficacy in important patient sub-populations, characterized by race, body mass index, symptom severity, and *Candida* species infection. Ibrexafungerp was well-tolerated in the pooled analysis.

- **Presented cumulative interim outcomes and all-cause mortality data in patients with refractory candidiasis treated with oral ibrexafungerp from the ongoing Phase 3 FURI study.** The analyses were presented during IDWeek 2022 held in Washington, D.C., October 19-23, 2022. Presentations included a platform overview of a cumulative interim analysis of 113 patients enrolled in the ongoing FURI Phase 3 study who had a variety of serious fungal infections, demonstrating 82.3% positive clinical outcomes in patients treated with ibrexafungerp. In addition, the poster highlighted all-cause mortality outcomes through 30 days post completion of ibrexafungerp treatment in 56 patients from the ongoing FURI study who had a diagnosis of invasive candidiasis or candidemia, demonstrating 94.6% overall survival.

Corporate Developments

- **On March 30, 2023, SCYNEXIS announced that it has entered into an exclusive agreement with GSK to commercialize and further develop BREXAFEMME (ibrexafungerp) for all indications.** Under the terms of the license agreement, upon deal close SCYNEXIS will receive an upfront payment of $90 million. The deal is expected to close in the second quarter of 2023.
    - SCYNEXIS will receive tiered royalties on cumulative net sales, and is also eligible to receive potential milestone-based payments totaling $503 million, including:
        - Regulatory approval milestone payments of up to $70 million.
        - Commercial milestone payments of up to $115 million based on first commercial sale in invasive candidiasis (U.S./EU).
        - Sales milestone payments of up to $242.5 million based on annual net sales, with a total of $77.5 million to be paid upon achievement of multiple thresholds up through $200 million; a total of $65 million to be paid upon achievement of multiple thresholds between $300 million and $500 million; and $50 million to be paid at each threshold of $750 million and $1 billion.
    - SCYNEXIS will be responsible for the execution and costs of the ongoing clinical studies of ibrexafungerp and will have the potential to receive up to $75.5 million in success-based development milestones, which are comprised of up to $65 million for the achievement of three interim milestones associated with SCYNEXIS's continued performance of the ongoing MARIO Study and $10.5 million for the successful completion of the MARIO Study.
    - SCYNEXIS retains rights to all other assets in the novel "fungerp" antifungal class. As part of this exclusive license agreement, GSK has been granted a right of first negotiation to these compounds.
    - This agreement is conditional upon customary conditions including review by the appropriate regulatory agencies under the Hart-Scott-Rodino Act.

- **On March 30, 2023, SCYNEXIS announced that it entered into an amendment of its previously reported Term Loan Agreement with Hercules Capital/SVB, pursuant to which SCYNEXIS will prepay in full all amounts owed.** The payment will be made in Q2 2023.

- **In November 2022, SCYNEXIS announced that researchers from Case Western Reserve University in Cleveland were awarded a competitive research grant of more than $3 million by the National Institutes of Health (NIH),** to investigate a second generation fungerp (SCY-247) developed by SCYNEXIS as a potential treatment for *C. auris,* a multidrug-resistant yeast that causes serious and often deadly infections.

- **On December 31, 2022, Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS, retired after more than seven years leading the Company.**

- **David Angulo, M.D., became President and Chief Executive Officer of SCYNEXIS and joined the Board of Directors effective January 1, 2023.**

- **In October 2022, Ivor Macleod joined SCYNEXIS as Chief Financial Officer**.

Fourth Quarter 2022 Financial Results

BREXAFEMME net product revenues increased to $1.4 million in Q4 2022, from $0.6 million in Q4 2021.

Cost of product revenue was $0.2 million in Q4 2022, compared to $0.2 million in Q4 2021.

Research and development expense for Q4 2022 was $7.8 million, compared to $7.7 million for Q4 2021.

Selling, General & administrative (SG&A) expenses for Q4 2022 increased to $16.0 million from $15.0 million for Q4 2021.

Total other income was $8.1 million for Q4 2022, versus total expense of $6.9 million for Q4 2021. During Q4 2022 and Q4 2021, SCYNEXIS recognized a non-cash gain of $9.1 million and a non-cash loss of $5.0 million, respectively, on the fair value adjustment of the warrant liabilities.

Net loss for Q4 2022 was $14.4 million, or $0.30 basic loss per share, compared to a net loss of $29.2 million, or $1.05 basic loss per share for Q4 2021.

Full Year 2022 Financial Results

BREXAFEMME generated net product revenue of $5.0 million for the full year 2022, compared to $1.1 million for the full year 2021.

Cost of product revenue was $0.6 million for the full year 2022 compared to $0.3 million for the full year 2021.

Research and development expense for the full year 2022 increased to $27.3 million from $23.8 million versus the comparable prior year. The increase of $3.5 million, or 14.7%, was primarily driven by an increase of $3.0 million in clinical development expense, an increase of $1.0 million in preclinical expense, an increase of $0.5 million in both salary and stock

compensation expense, offset by a decrease of $1.3 million in chemistry, manufacturing, and controls (CMC) expense, and a $0.2 million decrease in other research and development expense.

SG&A expense for the full year 2022 increased to $63.0 million from $49.9 million versus the comparable prior year. The increase of $13.0 million, or 26.1%, was primarily driven by a $8.6 million increase in commercial related expense, an increase of $1.6 million in salary and payroll related costs, and an increase of $1.5 million in professional fees, all primarily due to the costs recognized to support the commercialization of BREXAFEMME, an increase of $1.0 million in stock compensation expense, and an increase of $1.9 million in severance expense associated with the reduction in work force, offset in part by a decrease of $0.9 million in medical affairs expense and a $0.7 million decrease in business development expense due to the Hansoh license agreement entered into in 2021.

Total other income was $18.2 million for the full year 2022, versus $24.9 million for the comparable prior year. During the full years 2022 and 2021, SCYNEXIS recognized a non-cash gain of $22.3 million and a non-cash gain of $30.4 million, respectively, on the fair value adjustment of the warrant liabilities and non-cash gains of $1.3 million and $1.2 million, respectively, on the fair value adjustment of derivative liabilities.

Net loss for the full year 2022, was $62.8 million, or $1.47 per share, compared to net loss of $32.9 million, or $1.25 per share for the comparable prior year.

Cash Balance

Cash, cash equivalents and short-term investments totaled $73.5 million on December 31, 2022, compared to $104.5 million in cash and cash equivalents on December 31, 2021. Upon closure of the GSK transaction and receipt of the upfront payment of $90 million, based on its current projections, SCYNEXIS will have a cash runway of more than two years.

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 investigation and 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 granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the oral and IV 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. The European Medicines Agency (EMA) has granted ibrexafungerp Orphan Medicinal Product designation for the indication of IC. 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. SCYNEXIS is developing its lead

asset, ibrexafungerp, as a broad-spectrum, systemic antifungal for multiple fungal indications in both the community and hospital settings. The U.S. Food and Drug Administration (FDA) approved BREXAFEMME® (ibrexafungerp tablets) in June 2021, for treatment of 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 assets in the novel “fungerp” antifungal class are currently in preclinical 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, 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.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Years Ended December 31,	
	2022	**2021**
Revenue:		
Product revenue, net	$ 4,988	$ 1,113
License agreement revenue	103	12,050
Total revenue	5,091	13,163

Operating expenses:		
Cost of product revenue	628	312
Research and development	27,259	23,773
Selling, general and administrative	62,961	49,916
Total operating expenses	90,848	74,001
Loss from operations	(85,757)	(60,838)
Other (income) expense:		
Loss on extinguishment of debt	—	2,725
Amortization of debt issuance costs and discount	1,589	1,303
Interest income	(1,415)	(24)
Interest expense	5,198	2,660
Other income	(3)	(13)
Warrant liabilities fair value adjustment	(22,301)	(30,365)
Derivative liability fair value adjustment	(1,316)	(1,170)
Total other income	(18,248)	(24,884)
Loss before taxes	(67,509)	(35,954)
Income tax benefit	4,700	3,088
Net loss	$ (62,809)	$ (32,866)
Net loss per share – basic and diluted	$ (1.47)	$ (1.25)
Weighted average common shares outstanding – basic and diluted	42,613,510	26,384,713

The accompanying notes are an integral part of the financial statements.

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 45,814	$ 104,484
Short-term investments	27,689	—
Prepaid expenses and other current assets	2,503	3,569
Accounts receivable, net	2,101	861
Inventory, net	899	463
Restricted cash	55	—
Total current assets	79,061	109,377
Other assets	5,511	6,235
Deferred offering costs	73	150
Restricted cash	163	218
Intangible assets, net	408	1,056
Operating lease right-of-use asset (Note 10)	2,594	2,801

Total assets	**$ 87,810**	**$ 119,837**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,937	$ 7,848
Accrued expenses	5,628	5,698
Other liabilities, current portion (See Note 9)	5,771	—
Operating lease liability, current portion (Note 10)	282	70
Total current liabilities	17,618	13,616
Other liabilities	—	3,345
Warrant liabilities	18,644	18,062
Convertible debt and derivative liability (Note 9)	11,001	11,607
Loan payable (Note 9)	34,393	28,745
Operating lease liability (Note 10)	2,921	3,204
Total liabilities	84,577	78,579
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, authorized 5,000,000 shares as of December 31, 2022 and December 31, 2021; 0 shares issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value, 150,000,000 shares authorized as of December 31, 2022 and 100,000,000 shares as of December 31, 2021; 32,682,342 and 28,705,334 shares issued and outstanding as of December 31, 2022, and December 31, 2021, respectively	36	32
Additional paid-in capital	425,485	400,705
Accumulated deficit	(422,288)	(359,479)
Total stockholders' equity	3,233	41,258
Total liabilities and stockholders' equity	**$ 87,810**	**$ 119,837**

The accompanying notes are an integral part of the financial statements

SCYNEXIS

Source: Scynexis