November 9, 2022

SCYNEXIS Reports Third Quarter 2022 Financial Results and Provides Corporate Update

- SCYNEXIS recently announced new strategic direction to refocus its resources on the clinical development of ibrexafungerp for severe, hospital-based indications.
- Ivor Macleod, a 30-year biopharma veteran, joined SCYNEXIS as Chief Financial Officer.
- Marco Taglietti, M.D., to retire as President and Chief Executive Officer of SCYNEXIS and step down from the Board of Directors on December 31, 2022. David Angulo, M.D., Chief Medical Officer of SCYNEXIS will become President and Chief Executive Officer and join the Board effective January 1, 2023.
- BREXAFEMME® (ibrexafungerp tablets) prescriptions continued to grow in Q3 2022, increasing 13% over Q2 2022, generating net revenues of $1.6 million in Q3 2022, compared to $1.3 million in Q2 2022.
- Coverage for BREXAFEMME increased to 130 million, or 70% of commercially insured lives, with the addition of a major national Pharmacy Benefit Manager.
- SCYNEXIS ended the third quarter with a cash, cash equivalents and short-term investment balance of $96.1 million and has a projected cash runway into Q2 2024.
- SCYNEXIS will host a conference call today, **November 9, at 8:30 a.m. EST.**

JERSEY CITY, N.J., Nov. 09, 2022 (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 on September 30, 2022.

“Recently we have taken important steps to strategically refocus the Company on the successful development of ibrexafungerp in hospital-based indications where there is an urgent unmet need in patients with life-threatening infections,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “We believe there is great potential in this area. Separately, we are seeking a commercialization partner to maximize the value of BREXAFEMME in the U.S. We also look forward to the November 30, 2022, PDUFA date for BREXAFEMME, which, if approved, would make it the only antifungal for both the treatment of vulvovaginal candidiasis (VVC) and prevention of recurrent VVC.”

BREXAFEMME Commercial Update

- **BREXAFEMME achieved $1.6 million in net sales in Q3 2022.** According to IQVIA data, there were 5,785 total prescriptions for BREXAFEMME written in Q3 2022, a 13 percent increase of total prescriptions over Q2 2022.

- **BREXAFEMME** was prescribed by approximately 2,500 **individual healthcare professionals** (HCPs) in the third quarter, an increase of 11% over Q2 2022.

- **SCYNEXIS signed an agreement with an additional national Pharmacy Benefit Manager (PBM),** providing coverage for BREXAFEMME to an added 21 million commercially insured lives, and bringing total coverage to 130 million, or 70% of commercially insured lives.

- **In order to build on the positive sales trajectory to date and maximize BREXAFEMME's value, SCYNEXIS announced plans to out-license commercial rights** and is actively pursuing a U.S. commercialization partner for vulvovaginal candidiasis (VVC). During this process, SCYNEXIS has started winding down promotional activities, while keeping BREXAFEMME on the market and available to patients.

- **SCYNEXIS reported the Company's submission of a supplemental NDA for a second indication for BREXAFEMME for the prevention of recurrent VVC remains on track.** The U.S. Food and Drug Administration (FDA) granted the submission Priority Review and assigned the Prescription Drug User Fee Act (PDUFA) target decision date as November 30, 2022.

Ibrexafungerp Clinical Updates

- **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, and SCYNEXIS anticipates study completion and results to enable regulatory filing and potential approval for IC, including candidemia, in 2024

- **The FURI Phase 3 trial has surpassed its target enrollment, and study closure activities are progressing. Enrollment for the CARES Phase 3 trial is expected to be completed by the end of 2022**.

- **Enrollment continues for the SCYNERGIA** Phase 2 study evaluating the safety and efficacy of ibrexafungerp co-administered with voriconazole in patients with invasive pulmonary aspergillosis. Enrollment closure is anticipated by the end of 2022.

- **Following the positive Phase 1 data with the IV formulation** reported previously, SCYNEXIS is planning to begin a Phase 2 study of the IV formulation in 2023.

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 efficacy against various fungal infections, including those caused by azole-resistant *Aspergillus* species. Data from preclinical and clinical studies showcased in

the article provide rationale for the continued development of ibrexafungerp for the treatment and prevention of 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, a poster was presented highlighting 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.

- **Presented positive interim data in patients with refractory candidiasis treated with oral ibrexafungerp from the ongoing Phase 3 FURI study, as well as data from the ongoing CARES study of patients with *Candida auris* (*C. auris*) infections.** The interim analyses were presented during the Mycoses Study Group Education and Research Consortium (MSGERC) Biennial Meeting held in Albuquerque, N.M., September 7-9, 2022. Posters included: An interim analysis of 64 patients from the FURI study with refractory *Candida* infections, including failure of or resistance to previous standard-of-care antifungal therapy, demonstrating 56% of patients with complete or partial response, 27% had stable response, 9% showed disease progression, and 8% were indeterminate. SCYNEXIS also presented an interim analysis of 18 patients from the CARES study with invasive candidiasis/candidemia due to *C. auris*, demonstrating 78% of patients had a complete or partial response, 11% had stable response, one patient died of other causes, and one outcome was indeterminate.

- **Presented positive outcomes from its global Phase 3 CANDLE study investigating the safety and efficacy of oral ibrexafungerp for prevention of recurrent vulvovaginal candidiasis (RVVC),** also known as vaginal yeast infection. The results were presented during the Infectious Diseases Society for Obstetrics and Gynecology (IDSOG) Annual Meeting held in Boston August 4-6, 2022. The CANDLE study met its primary endpoint, with 65.4% of patients who received monthly single-day ibrexafungerp treatment achieving clinical success with no recurrence at all, either culture-proven, presumed or suspected, through Week 24. In addition, ibrexafungerp demonstrated superiority over placebo in preventing mycologically proven recurrence of RVVC through Week 24, a key secondary endpoint. No mycologically proven recurrence was detected in 70.8% of patients receiving ibrexafungerp. The advantage of ibrexafungerp over placebo was sustained over the three-month follow-up period and remained statistically significant in both primary and secondary endpoints

(p=0.034 and 0.029, respectively). In the study, ibrexafungerp was generally safe and well-tolerated. There were no serious drug-related adverse events, and no patients treated with ibrexafungerp discontinued therapy due to adverse events. The most commonly-reported adverse events, headaches and gastrointestinal in nature (i.e., diarrhea, nausea), were mostly mild and generally consistent with the current approved product label.

- **Presented positive outcomes from the CANDLE nested sub-study investigating oral ibrexafungerp in patients with recurrent vulvovaginal candidiasis (RVVC) who failed fluconazole treatment.** The results were presented during the International Society for the Study of Vulvovaginal Diseases (ISSVD) XXVI World Congress and International Vulvovaginal Disease Update 2022 held in Dublin, Ireland, July 15-20, 2022. Data show that 71% of 24 patients with recurrent vulvovaginal candidiasis (RVVC) who failed to respond to a three-day regimen of fluconazole achieved a substantial reduction or complete elimination of signs and symptoms after receiving a one-day treatment with ibrexafungerp.

Corporate Developments

- **In October 2022, Ivor Macleod joined the Company as Chief Financial Officer**. Mr. Macleod is an accomplished biopharma industry executive who brings deep experience spanning financial and operational roles.
- **In connection with the new strategic direction of the company, SCYNEXIS announced changes to its executive leadership team**:
    - Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS, will retire as of December 31, 2022.
    - David Angulo, M.D., Chief Medical Officer since 2015, will become President and Chief Executive Officer and join the Board of Directors, effective January 1, 2023.
    - Christine Coyne, Chief Commercial Officer, will transition from the Company as of November 30, 2022.

Third Quarter 2022 Financial Results

BREXAFEMME increased its net product revenues from $1.3 million in Q2 2022 to $1.6 million in Q3 2022.

Research and development expense for Q3 2022 was $6.4 million, compared to $4.4 million for Q3 2021. The increase is primarily attributed to increased costs associated with the MARIO clinical trial.

Selling, general & administrative (SG&A) expense for Q3 2022 increased to $16.7 million from $15.4 million for Q3 2021. The increase was primarily driven by increased commercial costs and professional fees recognized to support the commercialization of BREXAFEMME.

Total other expense was $7.8 million for Q3 2022, versus total other income of $18.8 million for Q3 2021. During Q3 2022 and Q3 2021, SCYNEXIS recognized a non-cash loss of $6.5 million and a non-cash gain of $18.8 million, respectively, on the fair value adjustment of the warrant liabilities.

Net loss for Q3 2022 was $29.6 million, or $0.62 basic loss per share, compared to a net loss of $600,000, or $0.02 basic loss per share for Q3 2021.

Cash Balance

Cash, cash equivalents and short-term investments totaled $96.1 million on September 30, 2022, compared to $104.5 million in cash and cash equivalents on December 31, 2021. Based upon its current operating plan, SCYNEXIS believes that its existing cash, cash equivalents and short-term investments will enable the Company to fund its operating requirements into Q2 2024.

Conference call and webcast details
A conference call to discuss the results will be held today at **8:30 a.m. EST**
Investors (domestic): 1-844-826-3033
Investors (international): 1-412-317-5185
Conference ID: 10172836

Webcast: HERE

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 U.S. Food and Drug Administration (FDA) granted ibrexafungerp 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. SCYNEXIS scientists are developing the company's 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. SCYNEXIS has initiated the launch of its first commercial product in the U.S., BREXAFEMME® (ibrexafungerp tablets). The U.S. Food and Drug Administration (FDA) approved BREXAFEMME on June 1, 2021. SCYNEXIS filed a supplemental New Drug Application (sNDA) to expand BREXAFEMME's labelling to include the prevention of recurrent vulvovaginal candidiasis, and the FDA assigned a target PDUFA action date of November 30, 2022, for this additional indication. In addition, late-stage clinical investigation of ibrexafungerp for the treatment of life-threatening invasive fungal infections in hospitalized patients is ongoing. 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: the expected benefits of the new corporate strategic direction; potential first approval of ibrexafungerp in hospital indications is expected in 2024; and a Phase 2 study of the IV formulation is planned for 2023; enrollment for the CARES Phase 3 trial is expected to be completed by the end of 2022; enrollment closure for the SCYNERGIA Phase 2 study is anticipated by the end of 2022; the expectation that the restructuring will result in decreased expenses and extend the company's cash runway into Q2 2024; and our potential to receive approval for the supplemental New Drug Application (sNDA) for a second indication in recurrent vulvovaginal candidiasis (RVVC) by November 30, 2022. 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; unexpected delays may occur in the timing of acceptance by the FDA of an NDA submission; SCYNEXIS' need for additional capital resources; and SCYNEXIS' reliance on third parties to 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.

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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,	
	2022	**2021**
Revenue:		
Product revenue, net	$ 1,557	$ 516
License agreement revenue	–	–
Total revenue	1,557	516

Operating expenses:		
Cost of product revenue	189	145
Research and development	6,430	4,401
Selling, general and administrative	16,739	15,411
Total operating expenses	23,358	19,957
Loss from operations:	(21,801)	(19,441)
Other expense (income):		
Amortization of debt issuance costs and discount	396	413
Interest income	(531)	(8)
Interest expense	1,379	1,019
Warrant liabilities fair value adjustment	6,497	(18,810)
Derivative liabilities fair value adjustment	42	(1,400)
Total other expense (income)	7,783	(18,786)
Loss before taxes	(29,584)	(655)
Income tax benefit	–	(50)
Net loss	$ (29,584)	$ (605)
Net loss per share attributable to common stockholders - basic		
Net loss per share - basic	$ (0.62)	$ (0.02)
Net loss per share attributable to common stockholders - diluted		
Net loss per share - diluted	$ (0.62)	$ (0.06)
Weighted average common shares outstanding - basic and diluted		
Basic	47,503,821	26,616,628
Diluted	47,503,821	27,754,828

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

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 68,620	$ 104,484
Short-term investments	27,470	-
Total current assets	103,565	109,377
Operating lease right-of-use asset	2,646	2,801
Total assets	112,293	119,837
Total current liabilities	14,264	13,616
Warrant liabilities, long term	27,730	18,062
Convertible debt and derivative liability	11,032	11,607
Loan payable	34,162	28,745
Operating lease liability, long term	2,998	3,204
Total liabilities	95,084	78,579

Total stockholders' equity	17,209	41,258
Total liabilities and stockholders' equity	$ 112,293	$ 119,837

Source: Scynexis