

May 12, 2022



# SCYNEXIS Reports First Quarter 2022 Financial Results and Provides Corporate Update

- BREXAFEMME® (ibrexafungerp tablets), launched in September 2021 for the treatment of vulvovaginal candidiasis (VVC), achieved almost 4,000 prescriptions with net revenues of \$0.7 million in Q1 2022. Expansion of the labeling to include prevention of recurrent VVC is anticipated by end of 2022.
- As of May 2022, BREXAFEMME was covered by commercial insurance plans representing 93 million, or 55% of commercially insured lives.
- SCYNEXIS initiated MARIO, a global Phase 3 study to evaluate ibrexafungerp as an oral step-down treatment for invasive candidiasis (IC) in the hospital setting and anticipates enrolling the first patient by the end of Q2 2022.
- Reported positive results from new interim analyses of the FURI and CARES trials highlighting oral ibrexafungerp's potency against severe fungal infections, with 83.2% of combined patients demonstrating a clinical response to oral ibrexafungerp.
- Based on a cash balance of \$95.2 million at March 31, 2022, and a \$45 million public offering (\$42 million net) in April, SCYNEXIS has a projected cash runway into Q1 2024.
- SCYNEXIS will host a conference call today, **May 12 at 8:30 a.m. EDT**

JERSEY CITY, N.J., May 12, 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 first quarter ended on March 31, 2022.

"Our Commercial organization is making solid progress toward bolstering prescription trends, and we are seeing the results of those concerted efforts," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "We recently strengthened our balance sheet, which enables us to enhance our commercial efforts in VVC and continue our R&D activities into 2024, as we build a broad antifungal franchise for ibrexafungerp across multiple indications."

## BREXAFEMME Commercial Update

- **BREXAFEMME delivered \$0.7 million in net sales in first quarter 2022.** According to IQVIA data, there were approximately 4,000 total prescriptions for BREXAFEMME written in Q1 2022. Total prescriptions have continued to grow in 2022 with 1,070 in

January, 1,328 in February and 1,579 in March.

- **BREXAFEMME** was prescribed by over **1,800 unique healthcare professionals** (HCPs) in the first quarter, and 55% of these doctors expanded their use and prescribed the treatment to multiple patients during this period, up from 40% last quarter.
- **Commercial insurance coverage of BREXAFEMME continues to expand.** As of April 2022, BREXAFEMME was covered by plans representing more than 93 million or 55% of commercially-insured lives.

### **Ibrexafungerp Clinical Updates**

- **Reported positive results from the fourth interim analysis of the FURI and CARES trials highlighting oral ibrexafungerp's potency against severe fungal infections.** The recent interim analyses included 39 new cases from FURI and eight new cases from CARES who completed treatment during the 12 months since the prior interim analyses. In the combined analysis of 131 patients, 83.2% of patients demonstrated a clinical response to oral ibrexafungerp. Of the 131 FURI and CARES study cases analyzed to date, 61.1% achieved a complete or partial response, or clinical improvement; and 22.1% achieved stable disease, which is a favorable outcome in patients with severe progressive fungal infections.
- **Reported positive results from the pivotal Phase 3 CANDLE study of oral ibrexafungerp for prevention of rVVC.** In this international trial of 260 patients with rVVC, defined as three or more episodes of vulvovaginal candidiasis (VVC) in the previous 12 months, patients initially received a three day regimen of fluconazole to treat their current infection, and responders were randomized in the prevention phase to receive either 300 mg ibrexafungerp BID or matching placebo one day a month, for six months. The study showed that 65.4% of patients receiving ibrexafungerp achieved clinical success by having no recurrence at all, either culture-proven, presumed or suspected, through Week 24 compared to 53.1% of placebo-treated patients ( $p=0.02$ ). The advantage of ibrexafungerp over placebo was sustained over the three-month follow-up period and remained statistically significant ( $p=0.034$ ). 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 events were headaches and gastrointestinal events, which were mostly mild and generally consistent with the current BREXAFEMME label. SCYNEXIS plans to submit the results in a supplemental NDA to the U.S. Food and Drug Administration (FDA) in the second quarter of 2022 and anticipates receiving approval by year-end.
- **SCYNEXIS initiated MARIO, a global Phase 3 study to evaluate ibrexafungerp as an oral step-down treatment for invasive candidiasis (IC) in the hospital setting.** Company anticipates enrolling the first patient by the end of Q2 2022.
- **Following the positive Phase 1 data with the IV formulation** reported previously, SCYNEXIS has begun to scale up manufacturing to enable additional IV trials.

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

- **Presented several posters highlighting details from interim analyses of data from its ongoing Phase 3 FURI and CARES studies investigating the potential of ibrexafungerp as a treatment for invasive candidiasis (IC) and candidemia, including infections caused by *Candida auris* (*C. auris*).** The posters were presented at the 32nd Annual European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) held in Lisbon, Portugal April 23-26, 2022. Posters included:
  - An interim analysis of the CARES study of 18 enrolled patients with candidemia and other infections caused by *Candida auris* (*C. auris*) treated for a mean duration of 18 days, 78% of patients showed complete or partial response and 11% had stable disease.
  - An interim analysis with combined data of 49 patients with invasive candidiasis and candidemia from the ongoing Phase 3 FURI (n=39) and CARES (n=10) studies. Aggregate data from the two studies showed that of the patients treated with ibrexafungerp, 68% had complete or partial response and 14% had stable disease.
  - Data presented from an *in vivo* mouse model of mucormycosis found that ibrexafungerp monotherapy demonstrated *in vivo* efficacy in treating both *Rhizopus delemar* and *Mucor circinelloides* infections in mice, consistent with other antifungals currently used against mucormycosis. Additionally, the study found that when ibrexafungerp was combined with liposomal amphotericin B (LAMB) or posaconazole (POSA), synergistic benefits were observed with a significant enhancement in median survival time and overall survival when compared to any one therapy alone (p<0.05).
- **Reported new positive outcomes in patients with refractory vulvovaginal candidiasis (VVC) treated with oral ibrexafungerp from the ongoing Phase 3 FURI study.** The new interim analysis was presented during the American College of Obstetricians and Gynecologists (ACOG) Annual Clinical & Scientific Meeting held in San Diego May 6-8, 2022. Ibrexafungerp showed positive results in difficult-to-treat VVC patients with severe fungal infections who were either intolerant to standard antifungal therapy or experienced refractory infections despite treatment. Of the 14 patients in the FURI study with refractory or relapsed cases of VVC treated with ibrexafungerp, 10 (71.4%) had successful clinical outcomes as judged by an independent Data Review Committee. Patients with VVC received 750 mg of oral ibrexafungerp (375 mg twice a day) every 72 hours for a total of three dosing days (Day 1, Day 4 and Day 7). In the study, ibrexafungerp was generally safe and well-tolerated with findings consistent with the existing product label.

## Corporate Developments

- **SCYNEXIS raised gross proceeds of \$45 million gross (\$42 million net) in an April 2022 public offering of common stock, pre-funded warrants, and warrants.**
- **SCYNEXIS received \$4.7 million in non-dilutive proceeds** in February 2022 from the sale of New Jersey State net operating losses to a third party.
- **SCYNEXIS received an additional \$5.0 million in non-dilutive proceeds** in March

2022 from the third tranche of the previously reported Term Loan Agreement with Hercules Capital/SVB upon achieving positive results from the Phase 3 CANDLE study of ibrexafungerp for the prevention of recurrent yeast infections.

## **First Quarter 2022 Financial Results**

BREXAFEMME generated net product revenue of \$0.7 million in the first quarter of 2022. The product was approved for sale by the FDA in June 2021 and launched in September 2021.

Cost of product revenue was \$100,000 in the first quarter of 2022.

Research and development expense for the first quarter of 2022 decreased to \$5.7 million from \$6.9 million versus the first quarter of 2021.

Selling, general & administrative (SG&A) expense for the first quarter of 2022 increased to \$14.6 million from \$6.7 million versus the first quarter of 2021. The increase was primarily driven by an increase in costs recognized to support the ongoing commercialization of BREXAFEMME.

Total other income was \$9.6 million for the first quarter of 2022, versus total other expense of \$2.0 million for the first quarter of 2021. During the first quarters of 2022 and 2021, SCYNEXIS recognized non-cash gains of \$10.0 million and \$1.3 million, respectively, on the fair value adjustment of the warrant liabilities and non-cash gains of \$1.0 million and non-cash losses of \$0.1 million, respectively, on the fair value adjustment of derivative liabilities.

Net loss for the first quarter of 2022, was \$5.5 million, or \$0.17 basic loss per share, compared to net loss of \$4.7 million, or \$0.18 basic loss per share for the first quarter of 2021.

## **Cash Balance**

Cash and cash equivalents totaled approximately \$95.2 million on March 31, 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 and cash equivalents, the net proceeds received from the April 2022 public offering, and the anticipated sales of BREXAFEMME will enable the Company to fund its operating requirements into Q1 2024.

## **Conference call and webcast details**

A conference call to discuss the results will be held at **8:30 a.m. EDT**

Investors (domestic): (877) 704-4453

Investors (international): (201) 389-0920

Conference ID: 13729053

Webcast: [https://viaid.webcasts.com/starthere.jsp?ei=1543196&tp\\_key=e943d8c4f4](https://viaid.webcasts.com/starthere.jsp?ei=1543196&tp_key=e943d8c4f4)

## **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. In addition, late-stage clinical investigation of ibrexafungerp for the prevention of recurrent Vulvovaginal Candidiasis (VVC) and the treatment of life-threatening invasive fungal infections in hospitalized patients is ongoing. For more information, visit [www.scynexis.com](http://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' accelerated growth and advancement toward our goal to build a broad antifungal franchise for ibrexafungerp across multiple indications; enlarging the prescriber base, expanding payer coverage, and growing BREXAFEMME revenues; our plan to file a supplemental New Drug Application (sNDA) in recurrent vulvovaginal candidiasis (rVVC) and receive approval for this label expansion by the end of 2022; enrollment in the MARIO study; advancement of our IV formulation; and our cash runway into the first quarter of 2024. 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 for additional indications; unexpected delays may occur in the timing of acceptance by the FDA of an NDA submission; the expected costs of studies and when they might begin or be concluded; SCYNEXIS' need for additional capital resources; and SCYNEXIS' reliance on third parties to conduct SCYNEXIS' clinical studies and 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)

|  | <b>Three Months Ended March</b> |             |
|--|---------------------------------|-------------|
|  | <b>31,</b>                      |             |
|  | <b>2022</b>                     | <b>2021</b> |
| Revenue:   |                                 |             |
| Product revenue, net                             | \$ 687                          | \$ –        |
| License agreement revenue                        | –                               | 12,050      |
| Total revenue                                    | 687                             | 12,050      |
| Operating expenses:                              |                                 |             |
| Cost of product revenue                          | 99                              | –           |
| Research and development                         | 5,735                           | 6,948       |
| Selling, general and administrative              | 14,591                          | 6,696       |
| Total operating expenses                         | 20,425                          | 13,644      |
| Loss from operations:                            | (19,738)                        | (1,594)     |
| Other expense (income):                          |                                 |             |
| Loss on extinguishment of debt                   | –                               | 2,725       |
| Amortization of debt issuance costs and discount | 390                             | 256         |
| Interest income                                  | (13)                            | (7)         |
| Interest expense                                 | 1,059                           | 214         |
| Other income                                     | (13)                            | –           |
| Warrant liabilities fair value adjustment        | (10,030)                        | (1,296)     |
| Derivative liabilities fair value adjustment     | (980)                           | 90          |

|  |                   |                   |
|--|-------------------|-------------------|
| Total other (income) expense                                     | (9,587)           | 1,982             |
| <b>Loss before taxes</b>   | (10,151)          | (3,576)           |
| Income tax (benefit) expense                                     | (4,700)           | 1,100             |
| <b>Net loss</b>  | <b>\$ (5,451)</b> | <b>\$ (4,676)</b> |
| Net loss per share attributable to common stockholders - basic   |                   |                   |
| Net loss per share - basic                                       | \$ (0.17)         | \$ (0.18)         |
| Net loss per share attributable to common stockholders - diluted |                   |                   |
| Net loss per share - diluted                                     | \$ (0.18)         | \$ (0.23)         |
| Weighted average common shares outstanding - basic and diluted   |                   |                   |
| Basic  | 32,051,228        | 25,802,700        |
| Diluted  | 33,189,428        | 26,523,920        |

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

|  | <b>March 31,<br/>2022</b> | <b>December<br/>31, 2021</b> |
|--|---------------------------|------------------------------|
| Cash and cash equivalents                  | \$ 95,210                 | \$ 104,484                   |
| Total current assets                       | 101,906                   | 109,377                      |
| Operating lease right-of-use asset         | 2,749                     | 2,801                        |
| Total assets                               | 111,562                   | 119,837                      |
| Warrant liabilities, current               | 40                        | -                            |
| Total current liabilities                  | 12,944                    | 13,616                       |
| Warrant liabilities, long term             | 7,921                     | 18,062                       |
| Convertible debt and derivative liability  | 10,817                    | 11,607                       |
| Loan payable                               | 33,713                    | 28,745                       |
| Operating lease liability, long term       | 3,138                     | 3,204                        |
| Total liabilities                          | 72,635                    | 78,579                       |
| Total stockholders' equity                 | 38,927                    | 41,258                       |
| Total liabilities and stockholders' equity | \$ 111,562                | \$ 119,837                   |



Source: Scynexis