# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, DC 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d) of the**
**Securities Exchange Act of 1934**

**Date of report (Date of earliest event reported): August 15, 2022**

# SCYNEXIS, Inc.

**(Exact Name of Registrant as Specified in Charter)**

| **Delaware** | **001-36365** | **56-2181648** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

**1 Evertrust Plaza, 13th Floor**
**Jersey City, New Jersey 07302-6548**
**(Address of Principal Executive Offices, and Zip Code)**

**(201)-884-5485**
**Registrant's Telephone Number, Including Area Code**

**N/A**
**(Former Name or Former Address, if Changed Since Last Report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| **Common Stock, par value $0.001** | **SCYX** | **Nasdaq Global Market** |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 2.02. Results of Operations and Financial Condition**

Attached as Exhibit 99.1 is a copy of a press release of SCYNEXIS, Inc., dated August 15, 2022, announcing certain financial results for the quarter ended June 30, 2022.

The information set forth in this Item 2.02., and Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits**

| **Exhibit No.** | **Description** |
|---|---|
| **99.1** | Press release announcing financial results for the quarter ended June 30, 2022, dated August 15, 2022. |
| **104** | Cover Page Interactive Data File (formatted as Inline XBRL). |

**Signature**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**SCYNEXIS, Inc.**

Date: August 14, 2022

By: /s/ Marco Taglietti
Name: Marco Taglietti, M.D.
Its: Chief Executive Officer

**SCYNEXIS Reports Second Quarter 2022 Financial Results and Provides Corporate Update**

- BREXAFEMME® (ibrexafungerp tablets) prescriptions in Q2 2022 increased 29 percent over Q1 2022, generating net revenues of $1.3 million in Q2 2022, compared to $0.7 million in Q1.
- SCYNEXIS filed a supplemental New Drug Application (sNDA) to expand BREXAFEMME's labelling to include the prevention of recurrent vulvovaginal candidiasis (RVVC); the FDA assigned a target PDUFA action date of November 30, 2022 for this additional indication.
- Enrollment has begun in two global Phase 3 trials: the MARIO study is evaluating ibrexafungerp as an oral step-down treatment for invasive candidiasis (IC) and the VANQUISH study is evaluating ibrexafungerp for VVC patients that have failed treatment with fluconazole therapy.
- Based on a cash balance of $118.7 million at June 30, 2022, SCYNEXIS has a projected cash runway into Q1 2024.
- SCYNEXIS will host a conference call today, **August 15, at 8:30 a.m. EDT.**

**JERSEY CITY, N.J.,** August 15, 2022 – 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 second quarter ended on June 30, 2022.

"We are pleased to see the improvements to the current sales trajectory, and we are well capitalized with a cash runway into the first quarter of 2024 to execute on the next important steps toward our goal of building a broad, long-lasting antifungal franchise," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "For the remainder of the year we will be focused on preparing for the approval of the recurrent VVC indication, while working to enroll invasive candidiasis patients into our MARIO study."

**BREXAFEMME Commercial Update**

- **BREXAFEMME delivered $1.3 million in net sales in Q2 2022.** According to IQVIA data, there were approximately 5,141 total prescriptions for BREXAFEMME written in Q2 2022, a 29 percent increase of total prescriptions over Q1 2022.
- **BREXAFEMME** was prescribed by over 2,200 individual healthcare professionals (HCPs) in the second quarter, an increase of 25% over Q1 2022.
- **Commercial insurance coverage of BREXAFEMME continues to expand.** As of June 2022, BREXAFEMME was covered by plans representing more than 109 million or 60% of commercially-insured lives, a 17% increase over the 93 million covered lives as of Q1 2022.

**Ibrexafungerp Clinical Updates**

- **In August 2022, SCYNEXIS announced that the U.S. Food and Drug Administration (FDA) accepted the Company's submission of a supplemental NDA for a labelling expansion for BREXAFEMME for the prevention of recurrent VVC.** The FDA granted

the submission Priority Review and assigned the Prescription Drug User Fee Act (PDUFA) target decision date as November 30, 2022.

- **Initiated enrollment in MARIO, a global Phase 3 study to evaluate ibrexafungerp as an oral step-down treatment for invasive candidiasis (IC) in the hospital setting.** SCYNEXIS anticipates study completion and results to enable regulatory filing and potential approval for IC, including candidemia, in 2024. If approved, oral ibrexafungerp would be the first non-azole oral therapy available for invasive candidiasis and would enable an IV-to-oral transition with a consistent mechanism of action. Like IV-only echinocandins, oral ibrexafungerp acts via glucan synthase inhibition, a mechanism which has been demonstrated to be the most effective for treating invasive *Candida* infections.

- **Initiated enrollment in a new Phase 3b, open-label, multicenter study (VANQUISH) to evaluate the efficacy, safety and tolerability of oral ibrexafungerp as a treatment for vulvovaginal candidiasis (VVC) in patients who have failed treatment with fluconazole, based on mycological and clinical outcomes.** The VANQUISH study will enroll approximately 150 patients with complicated VVC who have failed fluconazole treatment and who will receive 600 mg of oral ibrexafungerp for one, three or seven consecutive days determined by their underlying complicating condition including immunocompromised state. Complicated patients include patients with recurrent VVC, those with VVC caused by non-*albicans Candida* species, and those with diabetes, immunocompromising conditions (e.g., HIV), or immunosuppressive therapy (e.g., corticosteroids).

- **Achieved target enrollment of 200 patients for its Phase 3 FURI study evaluating oral ibrexafungerp for the treatment of patients with severe fungal infections who are either intolerant to standard antifungal therapy or experience refractory fungal infections despite treatment, including those caused by *Candida auris* (*C. auris*) .** SCYNEXIS anticipates study completion activities by the end of 2022 and also is on track to complete enrollment in the CARES trial during second half of 2022.

- **Following the positive Phase 1 data with the IV formulation** reported previously, SCYNEXIS is preparing for discussions with FDA regarding the next stage of development.

**Ibrexafungerp Scientific Presentations and Publications**

- **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 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.

- **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.

- **Presented positive interim analyses of data from its ongoing Phase 3 FURI and CARES studies**at the 32nd Annual European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) held in Lisbon, Portugal April 23-26, 2022. In 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 was conducted 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.

- **Additional preclinical data presented at ECCMID from an *in vivo* mouse model of pulmonary mucormycosis support ibrexafungerp as an effective potential treatment for mucormycosis.** The study also demonstrated *in vivo* efficacy of ibrexafungerp monotherapy 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 or posaconazole, synergistic benefits were observed with a significant enhancement in median survival time and overall survival when compared to any one therapy alone ($p<0.05$).

**Corporate Developments**

- SCYNEXIS raised gross proceeds of $45 million ($42 million net) in an April 2022 public offering of common stock, pre-funded warrants, and warrants.

**Second Quarter 2022 Financial Results**

BREXAFEMME increased its net product revenues from $0.7 million in Q1 2022 to $1.3 million in Q2 2022.

Research and development expense for Q2 2022 increased to $7.1 million from $4.7 million for Q2 2021.

Selling, general & administrative (SG&A) expense for Q2 2022 increased to $15.8 million from $12.8 million for Q2 2021. The increase was primarily driven by an increase in costs recognized to support the ongoing commercialization of BREXAFEMME.

Total other income was $8.4 million for Q2 2022, versus total other income of $15.0 million for Q2 2021. During Q2 2022 and Q2 2021, SCYNEXIS recognized non-cash gains of $9.7 million and $15.3 million, respectively, on the fair value adjustment of the warrant liabilities and non-cash gains of $0.2 million and $0.5 million, respectively, on the fair value adjustment of derivative liabilities.

Net loss for Q2 2022 was $13.3 million, or $0.31 basic loss per share, compared to a net gain of $1.7 million, or $0.06 basic income per share for Q2 2021.

**Cash Balance**

Cash and cash equivalents totaled $118.7 million on June 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 and cash equivalents, and the anticipated sales of BREXAFEMME, will enable SCYNEXIS to fund its operating requirements into Q1 2024.

**Conference call and webcast details**

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

Investors (domestic): (877) 704-4453
Investors (international): (201) 389-0920
Conference ID: 13730704

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: SCYNEXIS' goal to build a broad antifungal franchise for ibrexafungerp; SCYNEXIS' anticipation of the MARIO study completion and results, including to enable regulatory filing and potential approval for IC, including candidemia, in 2024; SCYNEXIS' expectations for the VANQUISH and CARES studies; and SCYNEXIS' expectation that its cash runway will be 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)**

| | Three Months Ended June 30, | |
|---|---|---|
| | **2022** | **2021** |
| Revenue: | | |
| Product revenue, net | $ 1,323 | $ – |
| License agreement revenue | – | – |
| Total revenue | 1,323 | – |
| Operating expenses: | | |
| Cost of product revenues | 144 | – |
| Research and development | 7,131 | 4,734 |
| Selling, general and administrative | 15,786 | 12,774 |
| Total operating expenses | 23,061 | 17,508 |
| Loss from operations: | (21,738 ) | (17,508 ) |
| Other expense (income): | | |
| Amortization of debt issuance costs and discount | 421 | 269 |
| Interest income | (181 ) | (6 ) |
| Interest expense | 1,231 | 445 |
| Other income | – | (3 ) |
| Warrant liabilities fair value adjustment | (9,682 ) | (15,271 ) |
| Derivative liabilities fair value adjustment | (182 ) | (462 ) |
| Total other income | (8,393 ) | (15,028 ) |
| **Loss before taxes** | (13,345 ) | (2,480 ) |
| Income tax benefit | – | (4,138 ) |
| **Net loss (income)** | $ (13,345 ) | $ 1,658 |
| Net (loss) income per share attributable to common stockholders - basic | | |
| Net (loss) income per share - basic | $ (0.31 ) | $ 0.06 |
| Net loss per share attributable to common stockholders - diluted | | |
| Net loss per share - diluted | $ (0.31 ) | $ (0.22 ) |
| Weighted average common shares outstanding - basic and diluted | | |
| Basic | 43,285,232 | 26,015,292 |
| Diluted | 43,285,232 | 26,487,973 |

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

| | **June 30, 2022** | **December 31, 2021** |
|---|---|---|
| Cash and cash equivalents | $ 118,691 | $ 104,484 |
| Total current assets | 125,676 | 109,377 |
| Operating lease right-of-use asset | 2,697 | 2,801 |
| Total assets | 135,612 | 119,837 |
| Total current liabilities | 16,012 | 13,616 |
| Warrant liabilities, long term | 21,232 | 18,062 |
| Convertible debt and derivative liability | 10,817 | 11,607 |
| Loan payable | 33,939 | 28,745 |
| Operating lease liability, long term | 3,071 | 3,204 |
| Total liabilities | 90,132 | 78,579 |
| Total stockholders' equity | 45,480 | 41,258 |
| Total liabilities and stockholders' equity | $ 135,612 | $ 119,837 |