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): May 12, 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. (the "Company"), dated May 12, 2022, announcing certain financial results for the quarter ended March 31, 2022.

The information set forth under this "Item 2.02. Results of Operations and Financial Condition," including the exhibit 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 March 31, 2022, dated May 12, 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: May 12, 2022

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

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 – 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://viavid.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.

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)

	Three Months Ended March 31,	
	2022	2021
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
Loss before taxes	(10,151)	(3,576)
Income tax (benefit) expense	(4,700)	1,100
Net loss	$ (5,451)	$ (4,676)
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)

	March 31, 2022	December 31, 2021
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