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): November 10, 2021

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 November 10, 2021, announcing certain financial results for the third quarter ended September 30, 2021.

The Company will conduct a conference call to review its financial results on November 10, 2021, at 8:30 a.m., Eastern Time.

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 third quarter September 30, 2021, dated November 10, 2021.
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: November 9, 2021

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

SCYNEXIS Reports Third Quarter 2021 Financial Results and Provides Corporate Update

- BREXAFEMME® (ibrexafungerp tablets) net sales of $0.5 million generated since August, with IQVIA reporting 1,006 prescriptions in partial Q3; momentum is continuing into Q4 with an additional 1,100 prescriptions reported in October.
- BREXAFEMME is now covered by commercial insurance plans representing more than 30% of commercially insured lives, exceeding internal expectations.
- Intravenous (IV) ibrexafungerp is ready to advance to the next stage of clinical development following successful Phase 1 trial evaluating safety and tolerability of liposomal IV formulation in healthy patients.
- Based on a $100 million cash balance at September 30 and operating plan, SCYNEXIS has a projected cash runway into 2023.

JERSEY CITY, N.J., November 10, 2021 – 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, 2021 and provided an update on recent clinical and corporate developments.

"We are rapidly advancing every element of the BREXAFEMME commercial launch according to plan, and our efforts have been paying off," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "Physician and payer receptivity to the BREXAFEMME value proposition is extremely encouraging as we continue to see an impressive upward trajectory of prescriptions and expanded coverage during the initial stages of the launch. We also look forward to reporting top-line data from our Phase 3 CANDLE study by early Q2 of next year. Furthermore, we are thrilled to announce the successful completion of the Phase 1 study of our new IV formulation of ibrexafungerp which will enable us to further expand the potential range of indications in the hospital setting."

BREXAFEMME Commercial Update

- **BREXAFEMME delivered $0.5 million in net sales in its first partial quarter of launch.** IQVIA data showed 1,006 total prescriptions for BREXAFEMME in Q3 2021, with nearly 700 in September, which was in line with the company's internal expectations for the first partial quarter of launch. There was a consistent week-over-week growth rate of prescriptions from early August to the end of the quarter, and a similar trajectory of growing positive momentum continuing into the fourth quarter, with IQVIA showing 1,100 BREXAFEMME prescriptions in October alone.
- **Insurance coverage of BREXAFEMME continues to grow.** BREXAFEMME is now covered by commercial insurance plans that represent more than 30% of commercially covered lives in the U.S.

Ibrexafungerp Clinical Updates

- **Enrollment is complete in the Phase 3 CANDLE study, investigating the efficacy and safety of oral ibrexafungerp for the prevention of recurrent vulvovaginal candidiasis (rVVC), for which there is no approved therapy in the U.S.** As previously reported, SCYNEXIS is on target to have last-patient/last-visit by the end of 2021 with top-line

results by early Q2 2022. A supplemental NDA submission is anticipated in Q2 2022 with a potential approval in late 2022.

- **Reported successful completion of Phase 1 clinical study of liposomal IV formulation of ibrexafungerp.** SCYNEXIS reported the successful completion of its Phase 1 randomized, double-blind, placebo-controlled single and multiple ascending dose study evaluating the safety, tolerability, and pharmacokinetics of the liposomal IV formulation of ibrexafungerp in healthy subjects. Dosing began in March 2021, and the last cohort completed in October 2021. Results from progressive ascending dosing to reach target exposure showed IV ibrexafungerp was generally well tolerated with no concerning safety findings, and SCYNEXIS is evaluating next steps toward the registrational program for this formulation.

- **Ongoing enrollment in the Phase 2 SCYNERGIA study for patients with invasive aspergillosis will be extended into 2022 to provide investigators impacted by the COVID-19 pandemic additional time to secure patients for this important trial.** SCYNERGIA, which is evaluating oral ibrexafungerp in combination with voriconazole for the treatment of invasive pulmonary aspergillosis, has not enrolled as rapidly as initially projected. The prioritization of hospital resources toward addressing the COVID-19 pandemic has impacted the ability of many institutions to focus on screening and enrolling patients into some clinical trials, including SCYNERGIA. With recent decreases in COVID-19 hospitalizations in some regions, enrollment is expected to accelerate over the next two quarters. Top-line results are anticipated in the second half of 2022.

Ibrexafungerp Scientific Presentations and Publications

- **Key findings from interim data analyses of SCYNEXIS' ongoing refractory invasive fungal infections (rIFI) program, which is comprised of two open-label Phase 3 studies (FURI and CARES), were presented at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID).** On July 12, 2021, presentations examining positive data from the third interim analysis of the FURI study and first interim analysis of the CARES study, showed oral ibrexafungerp's strong clinical activity and ability to treat severe fungal infections in the hospital setting, including the treatment of patients with refractory fungal disease and invasive candidiasis and candidemia due to *Candida auris*, a high-mortality infection. The results support continued enrollment in both open-label Phase 3 studies, with potential future submissions under the LPAD regulatory pathway.

- T**wo oral presentions on pooled data from SCYNEXIS Phase 3 VANISH program were presented at the Infectious Diseases Society for Obstetrics & Gynecology (IDSOG) 2021 Virtual Annual Meeting held on July 29-30, 2021.** The presentations showed consistent efficacy of oral ibrexafungerp in the treatment for VVC, particularly in important patient sub-populations.

- **Three presentations from an interim analysis of a Phase 3 open-label study (FURI) were presented at Virtual IDWeek 2021 on September 29-October 3, 2021.** These data support the favorable clinical activity of oral ibrexafungerp in severe hospital-based fungal infections across multiple serious fungal infections, including refractory candidiasis, oropharyngeal and esophageal candidiasis, and in *Candida* bone and joint infections.

- **Pre-clinical data supporting the potential of ibrexafungerp, to treat mucormycosis using an *in vivo* mouse model of mucormycosis, were presented at the 10th Trends**

in Medical Mycology (TIMM) meeting. On October 8-11, 2021, investigators presented findings, from an NIH-funded trial in which ibrexafungerp monotherapy demonstrated survival benefits equivalent to current standard of care treatments, including liposomal amphotericin B and posaconazole. Additionally, the study found when ibrexafungerp was combined with amphotericin B, synergistic benefits were observed with a significant enhancement in median survival time and overall survival when compared to any one therapy alone.

Corporate Developments

- On September 13, 2021, SCYNEXIS announced that its partner, Hansoh Pharmaceutical Group Company Limited (Hansoh Pharma), had filed an investigational new drug (IND) application with the National Medical Products Administration (NMPA) of the People's Republic of China for a Phase 3 study evaluating the efficacy and safety of ibrexafungerp for the treatment of VVC.

- On October 26, 2021, Eric Francois, Chief Financial Officer of SCYNEXIS, notified the company of his intent to resign to return to his prior career in investment banking. SCYNEXIS has engaged Danforth Advisors, LLC, which is providing an interim Chief Financial Officer until a permanent replacement is found. Mr. Francois will continue in his current role through November 19, 2021, to complete the company's third quarter reporting obligations and facilitate a smooth transition to Lawrence Hoffman, CPA, ESQ, of Danforth Advisors, who will serve as interim Chief Financial Officer.

Third Quarter 2021 Financial Results

BREXAFEMME generated a total of $0.5 million in net product revenues between the first week of August and September 30, 2021, which is in line with internal expectations.

Cost of product revenues was $0.1 million for the three months ended September 30, 2021 compared to $0.0 million for the three months ended September 30, 2020.

Research and development expense for the three months ended September 30, 2021 decreased to $4.4 million from $8.0 million for the three months ended September 30, 2020. The decrease of $3.6 million, or 45%, for the three months ended September 30, 2021 , was primarily driven by a decrease of $1.6 million in chemistry, manufacturing, and controls (CMC) expense, a decrease of $1.2 million in clinical development expense, a decrease of $0.6 million in regulatory expense, and a net decrease in other research and development expense of $0.2 million.

Selling, general & administrative expense for the three months ended September 30, 2021 increased to $15.4 million from $3.5 million for the three months ended September 30, 2020. The increase of $11.9 million, or 341%, for the three months ended September 30, 2021, was primarily driven by a $8.7 million increase in commercial related expense associated with the ongoing commercialization of BREXAFEMME, an increase of $1.3 million in salary related costs, an increase of $0.7 million in expense associated with increased information technology costs, an increase of $0.7 million in medical affairs expense, and a net increase of $0.5 million in other selling, general and administrative expense.

Total other income was $18.8 million for the three months ended September 30, 2021, compared to total other income of $12.4 million for the three months ended September 30, 2020. During the three months ended September 30, 2021 and 2020, SCYNEXIS recognized non-cash gains of $18.8 million and $7.8 million, respectively, on the fair value adjustment of the warrant liabilities

and during the three months ended September 30, 2021, and 2020, recognized non-cash gains of $1.4 million and $5.3 million on the fair value adjustment of the derivative liabilities, respectively.

Net loss for the three months ended September 30, 2021, was $0.6 million, or ($0.02) net loss per basic and ($0.06) net loss per diluted share, compared to net income of $0.9 million, or $0.09 net income per basic and ($0.28) net loss per diluted share for the three months ended September 30, 2020.

Cash and cash equivalents totaled $100.1 million on September 30, 2021, compared to $93.0 million in cash and cash equivalents on December 31, 2020. Based upon its existing operating plan, the company believes that its existing cash and cash equivalents, the sale of a portion of its New Jersey NOLs, and the anticipated sales of BREXAFEMME will enable SCYNEXIS to fund its operating requirements into 2023.

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 New Drug Application (NDA) for BREXAFEMME® (ibrexafungerp tablets) was approved by the U.S. Food and Drug Administration (FDA) on June 1, 2021. FDA also granted 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 has a projected cash runway into 2023, its expectations to report top-line data from its Phase 3 CANDLE study by early Q2 of next year, the new IV formulation of ibrexafungerp will enable the company to further expand the potential range of indications for ibrexafungerp in the hospital setting, its expectation to have the Phase 3 CANDLE study last-patient/last-visit by the end of 2021 with top-line results by early Q2

2022 and a supplemental NDA submission is anticipated in Q2 2022 with a potential approval in late 2022, enrollment in the Phase 2 SCYNERGIA study is expected to accelerate over the next two quarters and top-line results are anticipated in the second half of 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 for additional indications, including the IV formulation of ibrexafungerp currently in Phase 1; 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.

CONTACT:
Investor Relations
Irina Koffler
LifeSci Advisors
Tel: (646) 970-4681
ikoffler@lifesciadvisors.com

Media Relations
Gloria Gasaatura
LifeSci Communications
Tel: (646) 970-4688
ggasaatura@lifescicomms.com

SCYNEXIS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Three Months Ended September 30,	
	2021	2020
Revenue:		
Product revenue, net	$ 516	$ –
License agreement revenue	–	–
Total revenue	516	–
Operating expenses:		
Cost of product revenue	145	–
Research and development	4,401	8,030
Selling, general and administrative	15,411	3,481
Total operating expenses	19,957	11,511
Loss from operations:	(19,441)	(11,511)
Other expense (income):		
Amortization of debt issuance costs and discount	413	311
Interest income	(8)	(5)
Interest expense	1,019	330
Other expense	–	20
Warrant liabilities fair value adjustment	(18,810)	(7,786)
Derivative liabilities fair value adjustment	(1,400)	(5,290)
Total other income	(18,786)	(12,420)
(Loss) income before taxes	(655)	909
Income tax benefit	(50)	–
Net (loss) income	$ (605)	$ 909
Net (loss) income per share attributable to common stockholders - basic		
Net (loss) income per share - basic	$ (0.02)	$ 0.09
Net loss per share attributable to common stockholders - diluted		
Net loss per share - diluted	$ (0.06)	$ (0.28)
Weighted average common shares outstanding - basic and diluted		
Basic	26,616,628	10,627,618
Diluted	27,754,828	13,389,014

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

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 100,109	$ 93,041
Total current assets	103,933	98,206
Operating lease right-of-use asset	2,850	2,999
Total assets	109,882	102,536
Warrant liabilities, current	1,037	17,564
Total current liabilities	13,220	26,396
Warrant liabilities, long term	14,298	33,592
Convertible debt and derivative liability	10,805	16,516
Loan payable	28,579	–
Operating lease liability, long term	3,267	3,274
Total liabilities	72,268	79,778
Total stockholders' equity	37,614	22,758
Total liabilities and stockholders' equity	$ 109,882	$ 102,536