UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): June 10, 2024

SKYE BIOSCIENCE, INC.
(Exact name of registrant as specified in its charter)

Nevada	**000-55136**	**45-0692882**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

11250 El Camino Real, Suite 100, San Diego, CA 92130
(Address of principal executive offices)

(858) 410-0266
(Registrant's telephone number, including area code)

(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 obligations of the registrant under any of the following provisions.

☐ 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	**SKYE**	**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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§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 8.01 Other Events.

On June 10, 2024, Skye Bioscience, Inc. (the "Company," "we" and "our") issued a press release announcing that its Phase 2a clinical trial of SBI-100 Ophthalmic Emulsion ("OE") in patients with primary open-angle glaucoma or ocular hypertension did not meet its primary endpoint for lowering intraocular pressure. The Company intends to discontinue the clinical development of SBI-100 OE and all research and development associated with SBI-100 including its ophthalmology pipeline to direct its clinical development resources to its obesity program. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The press release will also be available under the "Investors" section of the Company's website.

FORWARD LOOKING STATEMENTS

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our product development, business strategy, the timing of clinical trials and published findings, and expected operating runway. Such statements and other statements in this Current Report on Form 8-K that are not descriptions of historical facts are forward-looking statements that are based on management's current expectations and assumptions and are subject to risks and uncertainties. If such risks or uncertainties materialize or such assumptions prove incorrect, our business, operating results, financial condition, and stock price could be materially negatively affected. In some cases, forward-looking statements can be identified by terminology including "anticipated," "plans," "goal," "focus," "aims," "intends," "believes," "can," "could," "challenge," "predictable," "will," "would," "may" or the negative of these terms or other comparable terminology. We operate in a rapidly changing environment, and new risks emerge from time to time. As a result, it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements the Company may make. Risks and uncertainties that may cause actual results to differ materially include, among others, our capital resources, uncertainty regarding the results of future testing and development efforts and other risks that are described in the Company's periodic filings with the Securities and Exchange Commission, including in the "Risk Factors" section of Skye's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. Except as expressly required by law, the Company disclaims any intent or obligation to update these forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

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.

SKYE BIOSCIENCE, INC.

Dated: June 10, 2024

/s/ Punit Dhillon

Name: Punit Dhillon

Title: Chief Executive Officer

Skye Concentrates Strategy and Clinical Development Focus on Nimacimab Metabolic Program

SBI-100 Ophthalmic Emulsion Phase 2a trial does not achieve target product profile; program discontinued

Phase 2 study of Nimacimab in obesity expected to start in Q3 2024

Cash runway extended into 2027

SAN DIEGO, June 10, 2024 – Skye Bioscience, Inc. (Nasdaq: SKYE) ("Skye" or the "Company"), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel classes of therapeutic drugs that modulate the endocannabinoid system, announced that its Phase 2a clinical trial of SBI-100 Ophthalmic Emulsion ("OE") in patients with primary open-angle glaucoma ("POAG") or ocular hypertension ("OHT") did not meet its primary endpoint for lowering intraocular pressure ("IOP"). Skye intends to discontinue clinical development and spending related to SBI-100 OE and any R&D associated with SBI-100, including its ophthalmology pipeline, and direct all clinical development resources to its metabolic program, extending its operating runway into 2027. Skye's Phase 2 obesity clinical trial for its differentiated CB1 inhibitor, Nimacimab, is expected to begin dosing in Q3 2024.

In this Phase 2a double-masked, randomized, placebo-controlled trial of SBI-100 OE, 56 patients with elevated IOP diagnosed with POAG or OHT received dosing of 1.0% or 0.5% concentrations of SBI-100 OE, or placebo, consisting of one drop in each eye, twice a day, for 14 days. The primary endpoint was to assess change in diurnal intraocular pressure in the treated arms vs. placebo. The study did not achieve a statistically significant improvement in IOP over placebo. The drug was safe and all treated patients completed the study with no early discontinuations due to adverse events.

"The results of this Phase 2a clinical trial of SBI-100 OE unfortunately did not meet our pre-set criteria for continuation and further development of this molecule as an alternative treatment for glaucoma and ocular hypertension. We will continue to evaluate the full data set and intend to publish findings," said Tu Diep, Skye's Chief Development Officer. "We thank the patients and investigators who supported our clinical investigation of SBI-100 OE in this study."

"In the last year we laid the groundwork for our metabolic program with the goals of diversifying our product portfolio's disease targets and therapeutic mechanisms, while significantly expanding our clinical and business opportunities. With this data outcome from our glaucoma program, we will now focus 100% of our efforts on broadening our metabolic clinical pipeline," said Punit Dhillon, Skye's CEO and Chair. "We believe that Nimacimab's unique mechanism of peripheral CB1 inhibition positions it to potentially contribute to the need for higher-quality, sustainable weight loss and better treatments for co-morbid conditions amidst an incretin-biased anti-obesity therapeutic landscape. We will look forward to sharing updates on this clinical program and advancing Nimacimab through to data in 2025."

About Nimacimab

Nimacimab is a first-in-class humanized monoclonal antibody that acts as a negative allosteric modulator to inhibit CB1 signaling in the periphery. Inhibition of CB1 has shown anti-fibrotic, anti-inflammatory, and metabolic mechanisms of action with potential to address a broad range of diseases with notable

unmet medical needs such as obesity, chronic kidney disease, and metabolic dysfunction-associated steatohepatitis (MASH).

About Skye Bioscience

Skye is focused on unlocking the pharmaceutical potential of the endocannabinoid system to treat diseases with metabolic, inflammatory, and fibrotic processes. Backed by specialist life science investors, Skye's strategy leverages biologic targets with substantial human proof of mechanism for the development of first-in-class therapeutics with significant clinical and commercial differentiation. Skye plans to start a Phase 2 clinical trial in obesity in Q3 2024 for Nimacimab, a negative allosteric modulating antibody that peripherally inhibits CB1, comparing monotherapy and combination arms of Nimacimab and a GLP-1R agonist. Clinical development of SBI-100 Ophthalmic Emulsion for glaucoma and ocular hypertension will be discontinued. Please visit: https://www.skyebioscience.com.

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FORWARD LOOKING STATEMENTS

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and Quarterly Report on Form 10-Q. Except as expressly required by law, Skye disclaims any intent or obligation to update these forward-looking statements.