

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): November 10, 2025

SKYE BIOSCIENCE, INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation)

000-55136

(Commission File Number)

45-0692882

(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 2.02 Results of Operations and Financial Condition.

On November 10, 2025, Skye Bioscience, Inc. (the “Company” or “Skye”) issued a press release providing a corporate update and reporting its financial results for the period ended September 30, 2025. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information contained or incorporated herein, including the press release filed as Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated November 10, 2025
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: November 10, 2025

/s/ Punit Dhillon

Name: Punit Dhillon

Title: Chief Executive Officer

Skye Bioscience Reports Third Quarter 2025 Financial Results and Business Update

- *Topline nimacimab Phase 2a study data showed clinically meaningful weight loss in nimacimab/semaglutide combination cohort versus semaglutide alone after 26 weeks of treatment; the data demonstrated a clean neuropsychiatric safety profile and no increase in gastrointestinal adverse events.*
- *Nimacimab plus semaglutide showed additional reduction in waist circumference of -3.2 cm vs. semaglutide alone.*
- *Rebound weight gain was lower in the 12-week post-treatment follow-up period in patients treated with nimacimab plus semaglutide vs. semaglutide alone.*

SAN DIEGO, CA, November 10, 2025 -- Skye Bioscience, Inc. (Nasdaq: SKYE) (“Skye” or the “Company”), a clinical stage biotechnology company developing next-generation molecules that modulate G-protein-coupled receptors to treat obesity, overweight, and related conditions, today reported financial results for the third quarter ended September 30, 2025, along with key accomplishments and upcoming milestones.

“As we obtain additional data from our CBeyond Phase 2a study, a holistic review provides us with additional confidence that nimacimab’s biology is active and has the potential to fill notable gaps in the obesity and overweight landscape in order to support a healthier weight loss journey for patients,” said Punit Dhillon, President & CEO of Skye. “With the positive combination data, we are shifting our focus to a combination development pathway while simultaneously planning to further understand nimacimab’s potential benefit in a monotherapy setting. We anticipate that forthcoming biomarker data and the readout from the 26-week extension will continue to build upon this story and provide further insights into nimacimab’s full potential as a metabolic therapy.”

Clinical Highlights: CBeyond™ Phase 2a Obesity Trial

- **Phase 2a Data Highlights:**
 - In October 2025, Skye reported 26-week topline data from its ongoing CBeyond Phase 2a study demonstrating a 29% relative increase in weight loss when nimacimab was dosed in combination with semaglutide compared to semaglutide alone.
 - At ObesityWeek 2025, Skye shared new weight rebound data highlighting that after treatment discontinuation nimacimab plus semaglutide blunted rebound weight gain compared to semaglutide alone (18.1% versus 49.8% weight regained over 12 weeks). Moreover, at 12 weeks post-treatment, the nimacimab plus semaglutide group maintained significant weight loss compared to the placebo group.
 - The nimacimab plus semaglutide combination also achieved an additional decrease in waist circumference of 3.2 cm (1.25 inches) compared to patients treated with semaglutide alone.
 - In the context of the obesity treatment landscape, we believe that this data highlights nimacimab’s potential as a combination or maintenance therapy by supplementing GLP-1 therapeutics to enhance weight loss and improve body composition by targeting fat loss, without adding gastrointestinal side effects.
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- **Extension Study Fully Enrolled:**

- In September, Skye completed the enrollment of its 26-week extension study. A total of 43 patients were enrolled, with 19 and 24 patients in the combination and monotherapy cohorts, respectively.
- Data from the 26-week extension is expected in Q1 2026 and will provide information on the potential full treatment duration of 52 weeks followed by a 12-week follow-up period.
- In the combination arms, patients will continue with blinded treatment with nimacimab or placebo and will continue receiving semaglutide (Wegovy®). Patients in the monotherapy arm will receive a higher dose of nimacimab (300 mg), which we expect will assist in refining our PK model.

Third Quarter 2025 Financial Results:

Balance Sheet and Cash Flow Highlights:

- Cash, cash equivalents and short-term investments totaled \$35.3 million as of September 30, 2025. The Company expects its current capital to fund projected operations and key clinical milestones into 2027, including completion of its Phase 2a extension study of nimacimab and certain manufacturing and clinical activities, initial manufacturing runs needed to start a subsequent trial, and planning activities. In addition, our runway supports our discovery, research and development efforts along with formulation and development work in preparation for nimacimab's later stage studies.

Operating Results:

- **R&D Expenses:**

Research and development (R&D) expenses for the three months ended September 30, 2025, were \$9.4 million, as compared to \$4.9 million for the same period in 2024. The increase was primarily due to contract manufacturing, clinical trial costs associated with our clinical study for nimacimab, discovery research and development expenses, salaries and stock based compensation expense, and consulting advisory and professional fees.

- **G&A Expenses:**

General and administrative (G&A) expenses for the three months ended September 30, 2025, were \$3.9 million, as compared to \$4.6 million for the same period in 2024. The decrease was primarily related to decreases in consulting, advisory and professional fees, recruitment fees, salaries, and stock based compensation expense.

- **Net Loss:**

Net loss for the three months ended September 30, 2025, totaled \$12.8 million, with non-cash stock-based compensation expense of \$1.9 million, compared to \$3.9 million for the same period in 2024, with non-cash stock-based compensation expense of \$1.9 million.

Conference Call Details

Skye will host a conference call to discuss its Q3 2025 results at 1:30 p.m. PT/4:30 p.m. ET today, November 10, 2025. The live streaming of the call can be accessed at the Skye investor relations website,

along with the Company's earnings press release, financial tables, and investor presentation. Following the call, a replay and transcript will be available at the same website.

ABOUT SKYE BIOSCIENCE

Skye is focused on unlocking new therapeutic pathways for metabolic health through the development of next-generation molecules that modulate G-protein coupled receptors. Skye's strategy leverages biologic targets with substantial human proof of mechanism for the development of first-in-class therapeutics with clinical and commercial differentiation. Skye is conducting a Phase 2a clinical trial (ClinicalTrials.gov: NCT06577090) in obesity for nimacimab, a negative allosteric modulating antibody that peripherally inhibits CB1. This study is also assessing the combination of nimacimab and a GLP-1R agonist (Wegovy®). For more information, please visit: www.skyebioscience.com. Connect with us on X and LinkedIn.

FORWARD LOOKING STATEMENTS

This press release includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements relating to: nimacimab's potential to fill notable gaps in the obesity and overweight landscape; nimacimab's potential as a combination or maintenance therapy by supplement GLP-1 therapies; future clinical development of nimacimab, including the initiation and design of any future clinical trials; the expected timing for reporting data from the Phase 2a extension study; the Company's cash runway. When used herein, words including “anticipate,” “believe,” “can,” “continue,” “could,” “designed,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “might,” “plan,” “planning,” “possible,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. All forward-looking statements are based upon the Company's current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. The Company may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important risks and uncertainties, including, without limitation, the initiation and design of any future clinical trials will be impacted by the Company's capital resources, the Company's ability to obtain additional sources of capital, program considerations and potentially other factors outside the Company's control; the potential for additional weight loss after 26 weeks may not ultimately be observed; there is no guarantee that higher dosing of nimacimab will achieve increased efficacy, and likewise it is possible that higher dosing will produce adversely different safety and tolerability results than those observed to date; the Company's dependence on third parties in connection with product manufacturing; research and preclinical and clinical testing; the Company's ability to advance, obtain regulatory approval of and ultimately commercialize nimacimab; competitive products or approaches limiting the commercial value of nimacimab; the timing and results of preclinical and clinical trials; the Company's ability to fund development activities and achieve development goals; the impact of any global pandemics, inflation, supply chain issues, government shutdowns, high interest rates, adverse regulatory changes; the Company's ability to protect its intellectual property; risks associated with the Company's common stock and the other important factors discussed under the caption “Risk Factors” in the Company's filings with the Securities and Exchange Commission, including in its Annual Report on Form 10-K for the year ended December 31, 2024, which are accessible on the SEC's website at www.sec.gov and the Investors section of the Company's website. Any such forward-looking statements represent management's estimates as of the date of this press release. While the Company may elect to update such forward-looking statements at some point in the future, except as required by law, it

disclaims any obligation to do so, even if subsequent events cause the Company's views to change. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses				
Research and development	\$ 9,357,444	\$ 4,883,337	\$ 30,892,454	\$ 10,908,538
General and administrative	3,907,090	4,638,927	12,375,567	13,171,547
Change in estimate for legal contingency	—	(4,553,468)	—	(4,553,468)
Total operating expenses	13,264,534	4,968,796	43,268,021	19,526,617
Operating loss	(13,264,534)	(4,968,796)	(43,268,021)	(19,526,617)
Other (income) expense				
Interest (income) expense	—	(90,766)	—	796,222
Interest and other income, net	(418,474)	(907,697)	(1,609,807)	(2,296,488)
Gains from asset sales	(91,400)	(72,837)	(180,763)	(1,217,978)
Other expense	—	801	—	2,200
Total other (income) expense, net	(509,874)	(1,070,499)	(1,790,570)	(2,716,044)
Loss before income taxes	(12,754,660)	(3,898,297)	(41,477,451)	(16,810,573)
Provision for income taxes	—	—	5,400	10,071
Net loss	<u>\$ (12,754,660)</u>	<u>\$ (3,898,297)</u>	<u>\$ (41,482,851)</u>	<u>\$ (16,820,644)</u>
Loss per common share:				
Basic	\$ (0.32)	\$ (0.10)	\$ (1.05)	\$ (0.48)
Diluted	\$ (0.32)	\$ (0.10)	\$ (1.05)	\$ (0.48)
Weighted average shares of common stock outstanding used to compute loss per share:				
Basic	39,665,927	38,819,387	39,654,512	35,317,352
Diluted	39,665,927	38,819,387	39,654,512	35,317,352

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	September 30, 2025 (Unaudited)	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	\$ 18,441,079	\$ 68,415,741
Short-term investments	16,871,229	—
Prepaid expenses	3,712,311	201,962
Other current assets	900,175	2,209,544
Total current assets	<u>39,924,794</u>	<u>70,827,247</u>
Property and equipment, net	1,033,965	1,432,752
Operating lease right-of-use asset	311,620	449,864
Other assets	53,910	53,910
Total assets	<u>\$ 41,324,289</u>	<u>\$ 72,763,773</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 2,825,005	\$ 569,252
Accrued payroll liabilities	920,774	1,114,255
Other current liabilities	2,366,123	654,201
Estimate for accrued legal contingencies and related expenses	2,054,357	1,818,751
Operating lease liability, current portion	201,638	182,428
Total current liabilities	<u>8,367,897</u>	<u>4,338,887</u>
Non-current liabilities		
Operating lease liability, net of current portion	120,207	273,162
Total liabilities	<u>8,488,104</u>	<u>4,612,049</u>
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.001 par value; 200,000 shares authorized at September 30, 2025 and December 31, 2024; no shares issued and outstanding at September 30, 2025 and December 31, 2024	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized at September 30, 2025 and December 31, 2024; 30,989,046 and 30,974,559 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	30,989	30,975
Additional paid-in-capital	205,237,719	199,070,421
Accumulated deficit	(172,432,523)	(130,949,672)
Total stockholders' equity	32,836,185	68,151,724
Total liabilities and stockholders' equity	<u>\$ 41,324,289</u>	<u>\$ 72,763,773</u>

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