March 10, 2026

Skye Bioscience Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Business Update

- Initiated higher-dose CBeyond Expansion Study (Part C) to generate higher-exposure human safety and pharmacokinetic data with 400 mg and 600 mg IV cohorts;
- Received written FDA Type C meeting minutes; feedback is informing key Phase 2b combination design elements and the Company's ongoing evaluation of a potential add-on development path with incretin therapy;
- Presented new body composition data demonstrating differentiated weight maintenance profile for patients that have discontinued combination therapy;
- Proof-of-concept preclinical data validates Skye's antigen-peptide conjugate platform, a single unimolecular therapeutic of nimacimab-GLP1RA that delivers additive weight-loss.

SAN DIEGO, March 10, 2026 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (NASDAQ: SKYE) ("Skye" or the "Company"), a clinical stage biopharmaceutical company pioneering next-generation molecules that modulate G-protein-coupled receptors to treat obesity, overweight, and related conditions, today reported financial results for the fourth quarter and full year ended December 31, 2025, along with key accomplishments and upcoming milestones.

"All of the data generated and reported in the past year along with the incremental data highlighted in todays release reinforces our strategy to develop nimacimab as a differentiated peripheral CB1 program designed to complement current incretin therapies and next-generation combination regimens. CBeyond confirmed the safety foundation and combination potential of peripheral CB1 inhibition, including a 22.3% mean weight loss at 52 weeks with nimacimab plus semaglutide and no plateau observed," said Punit Dhillon, President & CEO of Skye. "Just as important, CBeyond has now given us three practical learnings that shape what comes next: a meaningful combination signal, clean safety with no drug-related central nervous system toxicity at the tested dose, and a clear exposure question to solve in monotherapy. Our next step is straightforward: define the peripheral exposure-response at higher doses through the Expansion Study while using the FDA Type C feedback to shape a disciplined Phase 2b evaluation with clear dose-selection logic and success criteria across monotherapy and combination development."

Clinical Highlights

CBeyond Expansion Study (Part C): Higher-Exposure Evaluation

- Initiated the Expansion Study of CBeyond to assess preliminary safety and pharmacokinetics of nimacimab administered intravenously (IV) at doses higher than the subcutaneous (SC) regimen used in the main or extension portion of the Phase 2a

trial.
- The CBeyond Expansion Study includes two dose cohorts of nimacimab monotherapy (400 mg IV and 600 mg IV) compared to placebo administered weekly over 15 weeks, with a 12-week follow-up period.
- The CBeyond Expansion Study will enroll eight (8) participants per cohort randomized 3:1 for a total of 16 participants.
- Skye expects to report topline data from the CBeyond Expansion Study in Q4 2026.

Phase 2b (CBeyond 2): Regulatory Alignment and Protocol Finalization

- Completed an FDA Type C meeting and received written minutes. As Skye continues its review of the written feedback, the Company is using the minutes to sharpen its ongoing Phase 2b evaluation across key design elements (including dose, duration, endpoints and inclusion/exclusion criteria) and to assess the data package needed for potential combination development with an incretin therapy.
- Skye is evaluating a Phase 2b protocol that could study multiple doses of nimacimab as a monotherapy and in combination with an incretin therapy, using an adaptive design framework. Skye is continuing Phase 2b protocol development for the study.

CBeyond Phase 2a Obesity Trial: 26-week Outcomes

- Combination signal with incretin therapy: At 26 weeks, nimacimab plus semaglutide achieved an approximately 3% incremental weight-loss benefit versus semaglutide alone, with statistically significant improvements in lean-to-fat mass ratio and waist circumference; no plateau observed through week 26.
- Safety and tolerability: Nimacimab demonstrated placebo-like tolerability. In combination with semaglutide, there was no increase in gastrointestinal adverse events and no difference in neuropsychiatric adverse events compared to placebo or semaglutide alone.
- Dose/exposure learning: Nimacimab monotherapy at 200 mg weekly did not achieve the targeted weight-loss effect; Skye believes dose and exposure are the primary variables to solve and is testing higher peripheral exposure of nimacimab.

Interim 52-Week Combination Update

- In February 2026, Skye reported interim 52-week results in participants receiving nimacimab (200 mg dose) plus semaglutide (2.4 mg) combination, demonstrating 22.3% weight loss with no plateau observed, suggesting potential for further efficacy beyond one year and at higher nimacimab doses.
- Strong safety and tolerability profile maintained with no added gastrointestinal adverse events, and importantly, no drug-related neuropsychiatric adverse events.

Follow-up Period 13-Week Weight Regain Update

- Weight regain during off-treatment follow-up was lower by over 50% — nimacimab plus semaglutide cohort regained only 17.8% of lost weight vs. 37.3% for semaglutide

alone during 13-week off-therapy follow-up.
- Semaglutide weight regain profile similar to what has been reported in STEP-1 extension trial.
- Body composition data from 13-week follow-up period shows differentiated weight regain profile:
    - Combination cohort maintained fat mass loss and gained lean mass over 13-week off-treatment follow-up period.
    - Semaglutide cohort gained fat mass over 13-week off-treatment period.
    - Overall, combination cohort improved lean-to-fat mass ratio during 13-week off-treatment period.

Research & Development Highlights

- **Dosing Rationale & CBeyond Trial**
    - The 200 mg weekly CBeyond dose was selected based on availability of drug and comparable Phase 1 PK modeling and IC90-normalized comparisons to monlunabant's P2 mid-dose level — however, clinical outcomes diverged, with monlunabant achieving –6.3% weight loss versus nimacimab's –1.5%.
    - Translational biodistribution studies across mice, NHP, and published human data revealed that peripheral tissue exposure — not serum levels — is the key determinant of efficacy. Increased dosing achieves the tissue target engagement required for robust metabolic benefit, while maintaining minimal central nervous system exposure and a strong safety margin.
- **APC Pipeline**
    - Skye has developed an antibody-peptide conjugate (APC) program that unites nimacimab's unique CB1 inhibitory mechanism and extended half-life with the power of a GLP-1 receptor agonist in a single, unimolecular therapeutic, with a broader pipeline of novel bioconjugated molecules in development. In a preclinical proof-of-concept study, the APC dosed every three days matched the efficacy of a daily combination regimen and meaningfully exceeded either agent alone.

Manufacturing Readiness and CMC Development Highlights

- **Higher Volume Dose Delivery:** Licensed ENHANZE® (recombinant human hyaluronidase) drug delivery technology from Halozyme to enable patient-friendly, high volume subcutaneous administration.
- **Phase 2b Readiness:** Manufacturing of nimacimab drug substance in anticipation of the proposed Phase 2b trial supply continued in Q4 2025, and will continue in 2026, along with manufacturing of nimacimab drug product.
- **Optimizing Manufacturing Process for Supply & Competitive Cost of Goods (COGs):** Continued evaluating manufacturing process development options aimed at increasing batch output via improvements in upstream process productivity (titer) and downstream process yield.
- **Expanding and Strengthening the Supply Chain:** Advanced diligence and discussions with commercial contract manufacturing organizations to support

development and manufacturing of commercial-scale processes to enable cost-efficient supply of nimacimab for late-stage clinical trials and eventual commercial supply for the treatment of obesity, overweight, and related metabolic disorders.

- **Drug Formulation Optimization:** Continued progress in the development of a higher-concentration nimacimab formulation aimed at reducing SC injection volume in support of patient-friendly subcutaneous administration across a range of potential dose levels.
- **Advancing Toward Monthly Dosing:** Working to further evaluate and optimize nimacimab's formulation, administration and dosing paradigm to potentially enable the transition from weekly to monthly dosing with the intent to improve the patient experience, patient and physician adoption, and overall commercial attractiveness for improved positioning of nimacimab in obesity and overweight market entry dynamics.

Upcoming Anticipated Milestones

- **Q2 2026**: Present nimacimab preclinical data at scientific/medical conferences.
- **Q2 2026**: Analyst event in conjunction with the Scientific Sessions of the American Diabetes Association (ADA) in June to introduce additional clinical and preclinical data, market research insights, and other aspects of the Company's development program.
- **Q4 2026:** CBeyond Phase 2a Expansion Study topline results to 16-weeks.
- **Q4 2026**: Finalize Phase 2b (CBeyond 2) study design.

Fourth Quarter and Full Year 2025 Financial Results

Balance Sheet Highlights:

- Cash, cash equivalents, and short-term investments totaled $25.7 million as of December 31, 2025. The Company expects its current capital to fund projected operations and key clinical milestones through the fourth quarter of 2026, including completion of its Phase 2a extension study for nimacimab and initial manufacturing to enable the anticipated Phase 2b clinical study, but excluding the anticipated clinical cost of a proposed Phase 2b clinical study and additional anticipated drug manufacturing costs to supply any such Phase 2b study.

Operating Results:

- **R&D Expenses:**

  Research and development (R&D) expenses for the three months ended December 31, 2025, were $11.5 million, as compared to $7.8 million for the same period in 2024. The increase was primarily due to contracted manufacturing costs associated with our anticipated Phase 2b clinical trial for nimacimab in obesity and overweight, and employee related benefits. Increases were offset by a decrease in clinical costs, for the three months ended December 31, 2025 vs. 2024.

  R&D expenses for the year ended December 31, 2025, were $42.4 million, as compared to $18.7 million for the same period in 2024. The increase was primarily due

to contracted clinical study and manufacturing costs associated with our anticipated Phase 2b clinical trial for nimacimab in obesity and overweight. The remainder of the increase resulted from increases in discovery research efforts, salaries and stock based compensation expense, and consulting fees offset by a decrease in clinical study costs.

- **G&A Expenses:**

  General and administrative (G&A) expenses for the three months ended December 31, 2025, were $3.4 million, as compared to $4.6 million for the same period in 2024. The decrease was primarily related to non-cash incentive stock-based compensation, payroll, benefits and other employee costs, professional services including fees for tax, audit, financial advisory services, and other general business expenses.

  G&A expenses for the year ended December 31, 2025, were $15.8 million, as compared to $17.7 million for the same period in 2024. The decrease was primarily related to non-cash incentive stock-based compensation, professional services including fees for tax, audit, legal services, financial advisory services, patent prosecution for nimacimab intellectual property, other general business expenses.

- **Net Loss:**

  Net loss for the three months ended December 31, 2025, totaled $14.4 million, with non-cash share-based compensation expense of $1.6 million, compared to $9.7 million for the same period in ended 2024, with non-cash share-based compensation expense of $2.1 million.

  Net loss for the year ended December 31, 2025, totaled $55.9 million, with non-cash share-based compensation expense of $7.8 million, compared to $26.6 million for the year ended 2024, with non-cash share-based compensation expense of $8.3 million. The primary reason for the significant increase in net loss is related to a $20.7 million increase in contract manufacturing costs primarily related to the Phase 2a study extension and Phase 2b drug supply. In addition, during 2024 we recognized a $4.2 million gain from the partial derecognition of contingent liabilities and a $2.0 million gain from insurance recoveries related to legal proceedings, $3.0 million in interest income and a gain of $1.4 million from the sale of real estate.

Conference Call Details

Skye will host a conference call to discuss its FY 2025 and Q4 2025 results at 1:30 p.m. PT/4:30 p.m. ET today, March 10th. 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 and overweight 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 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, among others, regarding: Skye's expectations for nimacimab, including our clinical trial plans, enrollment in clinical trials, the potential applications of nimacimab; nimacimab's potential as a combination or maintenance therapy by supplementing GLP-1 therapies, the timing of initiating clinical trials and data read-outs, including the expected timing for reporting topline data from the Phase 2a extension study; the potential for Skye to develop a leading orthogonal platform to intensify incretin outcomes and help patients achieve more durable metabolic benefit; Skye's product development plan for nimacimab; and the Company's cash runway. Such statements and other statements in this press release 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," "expects," "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. Except as expressly required by law, Skye disclaims any intent or obligation to update these forward-looking statements.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31 (Unaudited)		Year Ended December 31	
	2025	**2024**	**2025**	**2024**
Operating expenses				

Research and development	$ 11,469,425	$ 7,793,156	$ 42,361,879	$ 18,701,694
General and administrative	3,426,119	4,622,945	15,801,686	17,725,741
Change in estimate for legal contingency	—	—	—	(4,234,717)
Income from insurance recovery	—	(1,750,000)	—	(2,000,000)
Total operating expenses	14,895,544	10,666,101	58,163,565	30,192,718
Operating loss	(14,895,544)	(10,666,101)	(58,163,565)	(30,192,718)
Other (income) expense				
Interest expense	—	(46,914)	—	749,308
Interest income	(274,096)	(732,274)	(1,883,903)	(3,028,762)
Gain from asset sale	(179,987)	(140,434)	(360,750)	(1,358,412)
Other expense	502	—	502	2,200
Total other (income) expense, net	(453,581)	(919,622)	(2,244,151)	(3,635,666)
Loss before income taxes	(14,441,963)	(9,746,479)	(55,919,414)	(26,557,052)
Provision for income taxes	—	—	5,400	10,071
Net loss	$(14,441,963)	$ (9,746,479)	$(55,924,814)	$(26,567,123)
Loss per common share				
Basic	$ (0.36)	$ (0.24)	$ (1.41)	$ (0.73)
Diluted	$ (0.36)	$ (0.24)	$ (1.41)	$ (0.73)
Weighted average shares of common stock outstanding used to compute loss per share:				
Basic	39,673,303	39,968,601	39,662,664	36,486,519
Diluted	39,673,303	39,968,601	39,662,664	36,486,519

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2025	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	$ 5,882,498	$ 68,415,741
Short-term investments	19,854,723	—
Prepaid expenses	504,890	201,962
Other current assets	852,036	2,209,544
Total current assets	27,094,147	70,827,247
Property and equipment, net	898,930	1,432,752
Operating lease right-of-use asset	266,646	449,864
Other assets	53,910	53,910
Total assets	**$ 28,313,633**	**$ 72,763,773**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 2,033,431	$ 569,252
Accrued payroll liabilities	1,269,474	1,114,255
Other current liabilities	2,643,840	654,201
Estimate for accrued legal contingencies and related expenses	2,069,067	1,818,751
Operating lease liability, current portion	189,647	182,428
Total current liabilities	8,205,459	4,338,887
Non-current liabilities		
Operating lease liability, net of current portion	83,999	273,162
Total liabilities	8,289,458	4,612,049
Commitments and contingencies		
Stockholders’ equity (deficit)		
Preferred stock, $0.001 par value; 200,000 shares authorized at December 31, 2025 and December 31, 2024; no shares issued and outstanding at December 31, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2025 and December 31, 2024; 33,378,139 and 30,974,559 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	33,379	30,975
Additional paid-in-capital	206,865,282	199,070,421
Accumulated deficit	(186,874,486)	(130,949,672)

Total stockholders' equity (deficit)	20,024,175	68,151,724
Total liabilities and stockholders' equity (deficit)	**$ 28,313,633**	**$ 72,763,773**

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