March 20, 2025

Skye Bioscience Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

- *Enrollment completed in Phase 2a CBeyond™ trial of CB1 inhibitor, nimacimab, in obesity and overweight*
- *Faster-than-expected enrollment enables full top-line Phase 2a data in late Q3/early Q4 2025, ahead of schedule; interim analysis removed*
- *Phase 2a dosing extended to 52 weeks to enhance long-term safety, tolerability, and efficacy data*
- *Cash runway projected through at least Q1 2027*

SAN DIEGO, March 20, 2025 (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, 2024, along with key accomplishments and upcoming milestones.

"Skye's prime accomplishment in 2024 was the initiation and rapid advancement of its comprehensive Phase 2a clinical study of nimacimab, a novel and differentiated CB1 inhibitor," said Punit Dhillon, President & CEO of Skye. "Maturation of the obesity therapeutics landscape, including expanding clinical evidence, M&A, and licensing, highlights the strategic importance of alternative mechanisms of action with attributes differentiated from incretins. We believe nimacimab's product profile is well-positioned to potentially fulfill critical unmet needs in this rapidly evolving therapeutic area.

"Our team showed discipline in capital allocation and focus in executing the Company's priorities. We surpassed our enrollment target ahead of schedule and have to-date executed the Phase 2a clinical plan on target and within our budget. We disclosed preclinical data in November 2024 which achieved significant dose-dependent weight loss, significant fat mass loss with lean mass preservation, and dose-dependent improvement in glucose tolerance. These outcomes are indicative of the potentially compelling attributes of Skye's highly peripherally-restricted CB1 inhibitor. In 2025 and beyond we will continue to apply this discipline and focus. We are enthusiastic about our updated clinical development plan, which will dramatically speed up our path to important 52-week treatment data from this extension study. Robust data in 2025 and 2026 will be valuable to various stakeholders and inform our regulatory engagement for future studies and decision-making."

Clinical Highlights: CBeyond™ Phase 2 Obesity Trial

- **CBeyond™ trial completed enrollment of 136 patients:** Study enrollment exceeded the initial target of 120, with data blinded through the completion of the 26-week

treatment and 13-week follow-up period.

- **Data Safety Monitoring Board reviews completed:** Two independent data safety monitoring board reviews have been successfully completed.
- **16 US Clinical Sites:** Welcomed a leading academic center of excellence in obesity as a clinical trial site during Q1 2025.
- **Accelerated timeline for 26-week data to late Q3/early Q4 2025:** Due to faster-than-anticipated enrollment the interim analysis has been removed and top line data is expected to be reported earlier than previously reported.
- **Expansion of the CBeyond™ trial:** To obtain 52 weeks of treatment data, the trial extension increases the originally planned 26 weeks of treatment to provide a longer-term assessment of safety, tolerability and efficacy. The protocol extension will provide for continued assessment of both the nimacimab monotherapy (primary endpoint) and the nimacimab/GLP-1 combination cohort (exploratory endpoint).

Research & Development Highlights

- **Vital role and sufficiency of peripherally-targeted CB1 inhibition:** Initial data from our diet-induced obesity model in mice released in November 2024 confirms that central CB1 inhibition is not required, and supports our hypothesis that nimacimab's peripherally-targeted CB1 inhibition drives significant weight loss and improved metabolic parameters, consistent with the compound's differentiated mechanism of action. An ongoing effort to characterize various attributes of nimacimab's capabilities as the most peripherally restricted CB1 inhibitor is expected to result in further preclinical data outcomes.
- **Broadening metabolic pathway understanding:** Current studies are leveraging translational models to demonstrate nimacimab's role in modulating hormones, inflammatory mediators, lipid metabolism, and glycemic control. We believe that additional data expected in the coming quarters may further clarify nimacimab's potential across a range of metabolic disorders.
- **Next-generation GPCR programs:** The Company is advancing development of next-generation GPCR-targeting molecules designed to address diverse metabolic disorders.

Manufacturing Highlights

- **Strengthening manufacturing:** Advancing activities in collaboration with contract manufacturing organizations to prepare for future clinical demand for nimacimab and further optimize its potential for the treatment of obesity, overweight, and related metabolic disorders.
- **Optimizing scale-up processes:** Evaluating modifications to upstream and downstream manufacturing processes to improve product yield and establish a commercial manufacturing process that is reliable and repeatable for large-scale commercial production.
- **Advancing toward monthly dosing:** We are working to optimize nimacimab's formulation and delivery to transition from weekly to monthly dosing to potentially improve patient experience, adherence, and commercial viability.

Corporate Highlights

- **Chief Development Officer promotion:** Skye recently promoted Tu Diep, to COO, recognizing his leadership throughout the Company. In this role, Mr. Diep is overseeing our development operations, CMC, corporate development and broader strategic execution.
- **Strengthened the internal and external chemistry, manufacturing, and controls team:** During 2024, Skye added to its team with seasoned individuals who bring significant experience in quality control and scale-up to nimacimab's manufacturing processes.
- **Resolved litigation matter:** Skye settled its insurance litigation case and received $2 million in cash proceeds from its former D&O carrier in the fourth quarter of 2024.

Upcoming Milestones

- **Q2 2025**: Nimacimab preclinical data being presented at scientific/medical conferences.
- **Q2 2025**: Analyst event in conjunction with the Scientific Sessions of the American Diabetes Association (ADA) in June to introduce additional preclinical data, market research insights, and other aspects of the Company's development program.
- **Late Q3/early Q4 2025**: Phase 2a CBeyond top-line data; full patient enrollment over 26 weeks of treatment and follow-up.

Fourth Quarter and Full Year 2024 Financial Results:

Balance Sheet Highlights:

- In January and March 2024, Skye closed two private investment in public equity transactions which collectively resulted in approximately $83.6 million in net proceeds.
- Cash and cash equivalents totaled $68.4 million on December 31, 2024. The Company expects its current capital to fund projected operations and key clinical milestones through at least Q1 2027, including completion of its Phase 2a study for nimacimab and Phase 2b manufacturing but excluding the Phase 2b clinical study or manufacturing activities necessary to supply a Phase 3 clinical study.
- Elimination of all related party balances, including the conversion of $5 million of debt to equity.

Operating Results:

- **R&D Expenses:**

  Research and development (R&D) expenses for the three months ended December 31, 2024, were $7.8 million, as compared to $1.6 million for the same period in 2023. The increase was primarily due to contracted clinical and manufacturing costs associated with our Phase 2 clinical trial for nimacimab in obesity and employee related benefits.

  R&D expenses for the year ended December 31, 2024, were $18.7 million, as

compared to $5.8 million for the same period in 2023. The increase was primarily due to contracted clinical and manufacturing costs associated with our Phase 2 clinical trial for nimacimab in obesity. The remainder of the increase resulted from increases in discovery research efforts, consulting fees, employee benefits driven by increases in headcount, and general expenses.

- **G&A Expenses:**

  General and administrative (G&A) expenses for the three months ended December 31, 2024, were $4.6 million, as compared to $2.5 million for the same period in 2023. The increase was primarily related to non-cash incentive stock-based compensation, payroll, benefits and other employee costs, professional services including fees for tax, audit, legal services, financial advisory services, and other general business expenses.

  G&A expenses for the year ended December 31, 2024, were $17.7 million, as compared to $7.9 million for the same period in 2023. The increase 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, 2024, totaled $9.7 million, with non-cash share-based compensation expense of $2.1 million, compared to $4.4 million for the year ended 2023, with non-cash share-based compensation expense of $0.6 million.

  Net loss for the year ended December 31, 2024, totaled $26.6 million, with non-cash share-based compensation expense of $8.3 million, compared to $37.6 million for the year ended 2023, with non-cash share-based compensation expense of $1.0 million. The primary reason for the significant decrease related to the acquisition of the nimacimab in-process research and development asset for $21.2 million during the year ended December 31, 2023, all of which was expensed upon acquisition. 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 2024 and Q4 2024 results at 1:30 p.m. PT/4:30 p.m. ET today, March 20th. 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 2 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 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: Skye's future plans and prospects, Skye's product development plan for nimacimab; the planned timing for reporting of data from Skye's phase 2a study of nimacimab in obesity; the therapeutic potential of nimacimab, including based on Skye's diet induced obesity mouse model; the potential applications of nimacimab; expectations around nimacimab's differentiated mechanism of action; expectations regarding the superior safety and tolerability profile of nimacimab relative to other small molecule CB1 inhibitors and the expected timing through which our current cash and cash equivalents will fund our operating plans. 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	
	2024	**2023**	**2024**	**2023**
Operating expenses				

Research and development	$ 7,793,156	$ 1,591,494	$ 18,701,694	$ 5,819,461
Cost to acquire IPR&D asset	—	—	—	21,215,214
General and administrative	4,622,945	2,494,763	17,725,741	7,852,340
Change in estimate for legal contingency	—	—	(4,234,717)	(151,842)
Income from insurance recovery	(1,750,000)	—	(2,000,000)	—
Total operating expenses	10,666,101	4,086,257	30,192,718	34,735,173
Operating loss	(10,666,101)	(4,086,257)	(30,192,718)	(34,735,173)
Other (income) expense				
Interest expense	(46,914)	430,135	749,308	906,270
Interest income	(732,274)	(50,305)	(3,028,762)	(99,974)
Wind-down costs	—	(46,157)	—	409,347
(Gain) loss from asset sale	(140,434)	—	(1,358,412)	307,086
Debt conversion inducement expense	—	—	—	1,383,285
Other expense (income)	—	—	2,200	(3)
Total other (income) expense, net	(919,622)	333,673	(3,635,666)	2,906,011
Loss before income taxes	(9,746,479)	(4,419,930)	(26,557,052)	(37,641,184)
Provision for income taxes	—	—	10,071	3,600
Net loss	$ (9,746,479)	$ (4,419,930)	$(26,567,123)	$(37,644,784)
Loss per common share				
Basic	$ (0.24)	$ (0.36)	$ (0.73)	$ (5.37)
Diluted	$ (0.24)	$ (0.36)	$ (0.73)	$ (5.37)
Weighted average shares of common stock outstanding used to compute loss per share:				
Basic	39,968,601	12,343,269	36,486,519	7,006,038
Diluted	39,968,601	12,343,269	36,486,519	7,006,038

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 68,415,741	$ 1,256,453
Restricted cash	—	9,080,202
Prepaid expenses	201,962	194,259
Other current assets	2,209,544	1,119,929
Total current assets	70,827,247	11,650,843
Property and equipment, net	1,432,752	43,276
Operating lease right-of-use asset	449,864	237,983
Other assets	53,910	8,309
Total assets	**$ 72,763,773**	**$ 11,940,411**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 569,252	$ 956,754
Accrued interest - related party	—	126,027
Accrued interest - legal contingency	—	234,750
Accrued payroll liabilities	1,114,255	888,381
Other current liabilities	654,201	991,805
Estimate for accrued legal contingencies and related expenses	1,818,751	6,259,246
Convertible note - related party, net of discount	—	4,371,998
Operating lease liability, current portion	182,428	72,038
Total current liabilities	4,338,887	13,900,999
Non-current liabilities		
Operating lease liability, net of current portion	273,162	171,230
Total liabilities	4,612,049	14,072,229
Commitments and contingencies		
Stockholders’ equity (deficit)		
Preferred stock, $0.001 par value; 200,000 shares authorized at December 31, 2024 and December 31, 2023; no shares issued and outstanding at December 31, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2024 and December 31, 2023; 30,974,559 and 12,349,243 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	30,975	12,349

Additional paid-in-capital	199,070,421	102,238,382
Accumulated deficit	(130,949,672)	(104,382,549)
Total stockholders' equity (deficit)	68,151,724	(2,131,818)
Total liabilities and stockholders' equity (deficit)	**$ 72,763,773**	**$ 11,940,411**

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