May 8, 2025

Skye Bioscience Reports First Quarter 2025 Results and Highlights Nimacimab Differentiation in Obesity

- *Nimacimab in combination with tirzepatide improves weight loss effect over tirzepatide alone, and shows comparable weight loss to monlunabant and tirzepatide alone in preclinical diet-induced obesity model*
- *In vitro data reported from new preclinical study highlights superior potency of peripherally restricted CB1 inhibitor, nimacimab, versus monlunabant when tested under pathological levels of CB1 agonists*
- *Expanded preclinical study data to be presented at ADA in June 2025*
- *Top-line data readout from CBeyond™ Phase 2a study of nimacimab expected late Q3/early Q4 2025*

SAN DIEGO, May 08, 2025 (GLOBE NEWSWIRE) -- 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 first quarter ended March 31, 2025, along with key accomplishments and upcoming milestones.

"In Q1, we made decisive progress across clinical operations and R&D," said Punit Dhillon, President & CEO of Skye. "Nimacimab continues to demonstrate a differentiated profile as a potential weight loss therapy, with a peripherally restricted mechanism that may set it apart from both GLP-1s and small-molecule CB1 inhibitors. We're advancing a body of preclinical and clinical evidence that supports its potential in reshaping the treatment landscape in obesity."

Clinical Highlights: CBeyond™ Phase 2 Obesity Trial

- **Clinical engagement remains strong:** Patients continue to receive active treatment and are progressing through scheduled follow-ups, supported by ongoing collaboration between the clinical team and study sites.
- **Safety reviews:** Data Safety Monitoring Committee has completed three reviews with no concerns raised. The study continues per protocol.
- **Institutional Review Board ("IRB") approval:** The IRB has approved the open-label study extension to 52 weeks. We are finalizing the study protocol with the FDA in preparation for enrollment.

Research & Development Highlights

- **Preclinical data:** Preclinical data further demonstrated the potential efficacy and potency of nimacimab.
- **Enhanced safety:** Diet-induced obesity ("DIO") mouse model data highlighted the

sufficiency of the highly-peripherally restricted CB1 inhibitor nimacimab--without central (brain) exposure--to drive weight loss, with similar efficacy compared to the less-peripherally restricted CB1 inhibitor monlunabant, which may be challenged by brain exposure and the risk of neuropsychiatric side effects.

  - Nimacimab combined with the dual GLP-1/GIP agonist tirzepatide achieved over 30% weight loss
  - Nimacimab alone produced 23.5% weight loss, comparable to monlunabant and tirzepatide alone in this study.

- **Superior potency:** *In vitro,* nimacimab's differentiated and favorable mechanism of CB1 inhibition showed superior potency versus the small molecule CB1 inhibitor monlunabant under the elevated concentrations of CB1 agonist associated with obesity.

First Quarter 2025 Financial Results:

Balance Sheet Highlights:

- Cash and cash equivalents and short-term investments totaled $59.2 million as of March 31, 2025. The Company expects its current capital to fund projected operations and key clinical milestones through at least Q1 2027, which includes the completion of its extended Phase 2a study for nimacimab and Phase 2b manufacturing but excluding the Phase 2b clinical study and manufacturing activities necessary to supply later stage studies.

Operating Results:

- **R&D Expenses:**

  Research and development (R&D) expenses for the three months ended March 31, 2025, were $7.2 million, as compared to $1.9 million for the same period in 2024. The increase was primarily due to contract manufacturing and clinical trial costs associated with our Phase 2a clinical study for nimacimab, salaries and stock based compensation, consulting and depreciation expense.

- **G&A Expenses:**

  General and administrative (G&A) expenses for the three months ended March 31, 2025, were $4.6 million, as compared to $4.2 million for the same period in 2024. The increase was primarily related to investor relations, marketing and communication costs and consulting and advisory fees.

- **Net Loss:**

  Net loss for the three months ended March 31, 2025, totaled $11.1 million, with non-cash share-based compensation expense of $2.2 million, compared to $5.0 million for the same period in 2024, with non-cash share-based compensation expense of $2.5 million.

Conference Call Details

Skye will host a conference call to discuss its Q1 2025 results at 1:30 p.m. PT/4:30 p.m. ET today, May 8, 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 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. 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. These forward looking statements include, but are not limited to: (i) statements regarding the superior safety and tolerability profile of nimacimab relative to other small molecule CB1 inhibitors, (ii) statements relating to any expectations regarding the efficacy and therapeutic potential of nimacimab as a monotherapy or in combination with a GLP-1 targeted drug, including expectations based on preclinical DIO models, (iii) statements regarding nimacimab’s potential to change weight loss standards of care, (iv) statements regarding superior potency of nimacimab to other small molecule CB1 inhibitors, such as monlunabant, based on nimacimab’s mechanism of action (v) statements regarding the timing of receipt of topline data from Skye’s Phase 2 obesity study of nimacimab and (vi) statements regarding the timing of enrollment for the 52-week enrollment study. 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. 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, Skye disclaims any intent or obligation to update these forward-looking statements.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses		
Research and development	$ 7,197,257	$ 1,946,450
General and administrative	4,562,305	4,205,800
Total operating expenses	11,759,562	6,152,250
Operating loss	(11,759,562)	(6,152,250)
Other expense (income)		
Interest expense	1,452	436,936
Interest income	(619,054)	(427,554)
Gain on sale of asset	—	(1,145,141)
Other (income) expense	(40,641)	1,040
Total other (income) expense, net	(658,243)	(1,134,719)
Loss before income taxes	(11,101,319)	(5,017,531)
Provision for income taxes	2,000	2,000
Net loss	$(11,103,319)	$ (5,019,531)
Loss per common share:		
Basic	$ (0.28)	$ (0.18)
Diluted	$ (0.28)	$ (0.18)
Weighted average shares of common stock outstanding used to compute loss per share:		
Basic	39,651,888	27,999,901
Diluted	39,651,888	27,999,901

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	March 31, 2025	December 31, 2024
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 46,421,299	$ 68,415,741
Short-term investments	12,802,650	—
Prepaid expenses	575,382	201,962
Other current assets	3,228,450	2,209,544
Total current assets	63,027,781	70,827,247
Property and equipment, net	1,304,148	1,432,752
Operating lease right-of-use asset	407,401	449,864
Other assets	53,910	53,910
Total assets	$ 64,793,240	$ 72,763,773
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,713,832	$ 569,252
Accrued payroll liabilities	656,131	1,114,255
Other current liabilities	847,849	654,201
Estimate for accrued legal contingencies and related expenses	1,913,003	1,818,751
Operating lease liability, current portion	188,645	182,428
Total current liabilities	5,319,460	4,338,887
Non-current liabilities		
Operating lease liability, net of current portion	223,466	273,162
Total liabilities	5,542,926	4,612,049
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 200,000 shares authorized at March 31, 2025 and December 31, 2024; no shares issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at March 31, 2025 and December 31, 2024; 30,974,559 and 30,974,559 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	30,975	30,975
Additional paid-in-capital	201,272,330	199,070,421
Accumulated deficit	(142,052,991)	(130,949,672)
Total stockholders' equity	59,250,314	68,151,724

Total liabilities and stockholders' equity	**$ 64,793,240**	**$ 72,763,773**

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