November 7, 2024

Skye Bioscience Reports Third Quarter 2024 Financial Results and Recent Highlights

SAN DIEGO, Nov. 07, 2024 (GLOBE NEWSWIRE) -- Skye Bioscience, Inc. (NASDAQ: SKYE) ("Skye" or the "Company"), a clinical-stage biopharmaceutical company focused on unlocking new therapeutic pathways for metabolic health, today reported financial results for the third quarter ended September 30, 2024, and highlighted recent corporate achievements.

"The third quarter marked an important transition for Skye as a metabolic-focused company with the launch of our Phase 2 obesity clinical trial for nimacimab. We believe our truly peripherally-restricted CB1 inhibitor has the differentiated attributes necessary to realize the unique benefits of this class of drug within the overall obesity landscape," said Punit Dhillon, CEO of Skye. "We also recently announced new preclinical data from a diet-induced obesity (DIO) model in mice. Nimacimab achieved significant dose-dependent weight loss of up to 16% compared to vehicle, highlighting the prominent role of peripherally-driven CB1 inhibition to induce weight loss and other metabolic benefits without relying on central CB1 inhibition and its risk of neuropsychiatric adverse events.

"In the first half of the year we built on the foundation of the company in terms of people, capital, systems and preparation. Now we are focused on executing our development and clinical milestones in 2025, including interim Phase 2 data in Q2 of 2025."

Key Corporate and Clinical Program Highlights

CBeyond Phase 2 Obesity Trial for Peripheral CB1 Inhibitor Advancing

Skye started enrolling patients in its Phase 2 study of nimacimab in August 2024. Nimacimab, a first-in-class CB1-inhibiting monoclonal antibody, is a negative allosteric modulator that acts as both an inverse agonist and antagonist. Study design:

- Randomized, doubled-blind, placebo-controlled
- Primary endpoint: designed to demonstrate an 8% difference in mean weight loss of nimacimab versus placebo at 26 weeks, with 13 weeks of follow-up
- Secondary and exploratory endpoints will evaluate safety, tolerability, neuropsychiatric and cognitive outcomes, and change in body composition by DEXA, and is also assessing synergistic outcomes when nimacimab is combined with semaglutide, a GLP-1 receptor agonist
- Interim data targeted for Q2 2025: 50% enrollment of planned 120 patients after 26 weeks of treatment
- Topline data targeted for Q4 2025 after full enrollment.

New Preclinical Data Provides Insight into Mechanism of CB1 Inhibition and Nimacimab

To evaluate and provide more insight into the mechanisms of CB1 inhibition and the unique elements of its differentiated CB1 inhibitor, Skye developed a novel diet-induced obesity (DIO) model. Results:

- DIO model uses a transgenic mouse expressing the human CB1 receptor (hCB1R)
- Dose-dependent weight loss with nimacimab of 4.5%, 11.4% and 16.0% compared to vehicle
- Significant fat mass loss with lean mass preservation
- Dose-dependent improvement in glucose tolerance
- Preliminary results provide first direct evidence supporting hypothesis that peripheral CB1 inhibition is the primary driver of weight loss whereas central CB1 inhibition contributes minimally to efficacy yet promotes neuropsychiatric adverse events. Further data will be forthcoming. A recording of this presentation, conducted as a satellite event at ObesityWeek 2024, is available here.

Corporate Highlights

- Skye appointed Dr. Puneet Arora as its Chief Medical Officer. Dr. Arora is an endocrinologist with extensive metabolic experience.
- Skye recently announced the appointment of Paul Grayson as its new Chairman of the Board.
- Subsequent to quarter end, the United States Court of Appeals for the Ninth District vacated the judgment with respect to an outstanding litigation matter. As a result, the Company will be able to recover the $9 million restriction on its cash related to the appeal bond, which is expected to be released before year-end.

Third Quarter 2024 Financial Highlights:

Cash Position: Cash and cash equivalents totaled $76.5 million, including restricted cash of $9.1 million on September 30, 2024. The Company expects its current capital to fund projected operations through Q3 2027.

R&D Expenses: Research and development (R&D) expenses for the third quarter of 2024 were $4.9 million, as compared to $1.3 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 employee benefits, travel, and consulting fees driven by increases in headcount.

G&A Expenses: General and administrative (G&A) expenses for the third quarter of 2024 were $4.6 million, as compared to $2.2 million for the same period in 2023. The increases were primarily related to non-cash incentive stock-based compensation, professional services and fees for tax, audit, and legal services related to our required regulatory filings, financial advisory services, and patent prosecution for the nimacimab IP. These costs were offset by a period over period decrease in litigation related legal fees.

Net Loss: Net loss for the third quarter of 2024 totaled $3.9 million, with non-cash share-based compensation expense of $1.9 million, compared to $24.9 million for the third quarter of 2023, with non-cash share-based compensation expense of $0.2 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 three months ended September 30, 2023, all of which was expensed upon acquisition. In addition, we recognized $1 million in interest income and $4.6 million in income from the partial derecognition of liabilities and the recovery of losses related to our legal proceedings.

Conference Call Details

Skye will host a conference call to discuss its results at 1:30 p.m. PT/4:30 p.m. ET today, November 7th. The live webcast 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 our product development for nimacimab, reporting of interim and final data from Skye's phase 2 study of nimacimab in obesity, the timing of clinical trials for nimacimab, the therapeutic potential of nimacimab (including based on Skye's DIO model) 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 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
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses				
Research and development	$ 4,883,337	$ 1,254,653	$ 10,908,538	$ 4,227,967
Cost to acquire IPR&D asset	—	21,215,214	—	21,215,214
General and administrative	4,638,927	2,235,899	13,171,547	5,357,577
Change in estimate for legal contingencies	(4,553,468)	—	(4,553,468)	(151,842)
Total operating expenses	4,968,796	24,705,766	19,526,617	30,648,916
Operating loss	(4,968,796)	(24,705,766)	(19,526,617)	(30,648,916)
Other expense (income)				
Interest (income) expense	(90,766)	271,307	796,222	476,135
Interest income	(907,697)	(16,562)	(2,296,488)	(49,669)
(Gain) loss from asset sales	(72,837)	—	(1,217,978)	307,086
Debt conversion inducement expense	—	—	—	1,383,285
Wind-down costs	—	(14,677)	—	455,504
Other expense (income)	801	—	2,200	(3)
Total other (income) expense, net	(1,070,499)	240,068	(2,716,044)	2,572,338
Loss before income taxes	(3,898,297)	(24,945,834)	(16,810,573)	(33,221,254)
Provision for income taxes	—	—	10,071	3,600
Net loss	$ (3,898,297)	$ (24,945,834)	$ (16,820,644)	$ (33,224,854)

Loss per common share:				
Basic	$ (0.10)	$ (3.17)	$ (0.48)	$ (6.38)
Diluted	$ (0.10)	$ (3.17)	$ (0.48)	$ (6.38)
Weighted average shares of common stock outstanding used to compute earnings per share:				
Basic	38,819,387	7,880,546	35,317,352	5,207,411
Diluted	38,819,387	7,880,546	35,317,352	5,207,411

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 67,412,614	$ 1,256,453
Restricted cash	9,080,202	9,080,202
Prepaid expenses	664,604	194,259
Other current assets	2,650,809	1,119,929
Total current assets	79,808,229	11,650,843
Property and equipment, net	1,516,612	43,276
Operating lease right-of-use asset	184,509	237,983
Other assets	26,310	8,309
Total assets	**$ 81,535,660**	**$ 11,940,411**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 780,025	$ 1,155,785
Accrued interest – related party	—	126,027
Accrued interest – legal contingency	—	234,750
Accrued payroll liabilities	903,271	888,381
Other current liabilities	2,065,658	998,552
Estimate for accrued legal contingencies and related expenses	1,792,337	6,053,468
Convertible note – related party, net of discount	—	4,371,998

Operating lease liability, current portion	82,932	72,038
Total current liabilities	5,624,223	13,900,999
Noncurrent liabilities		
Operating lease liability, net of current portion	108,062	171,230
Total liabilities	5,732,285	14,072,229
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 200,000 shares authorized at September 30, 2024 and December 31, 2023; no shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at September 30, 2024 and December 31, 2023; 30,338,290 and 12,349,243 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	30,338	12,349
Additional paid-in-capital	196,976,230	102,238,382
Accumulated deficit	(121,203,193)	(104,382,549)
Total stockholders' equity	75,803,375	(2,131,818)
Total liabilities and stockholders' equity	**$ 81,535,660**	**$ 11,940,411**

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