August 9, 2024

Skye Bioscience Reports Second Quarter 2024 Financial Results and Recent Highlights

Advancement of clinical and regulatory steps enable the expected initiation of Phase 2 obesity clinical trial for nimacimab peripheral CB1 inhibitor in Q3 2024

SAN DIEGO, Aug. 09, 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 second quarter ended June 30, 2024, and highlighted recent corporate achievements.

"Our strategic acquisition of nimacimab in August 2023 has propelled Skye into the metabolic landscape, where there is a need to provide patients with obesity more tolerable and sustainable therapeutic alternatives to manage weight loss and address comorbid conditions," said Punit Dhillon, CEO of Skye. "In Q2, at our event, 'Metabolic Rewiring with CB1 Inhibition,' we outlined our *CBeyond*™ Phase 2 clinical trial design and highlighted nimacimab's differentiators, which we believe competitively position Skye. During the second quarter of 2024, we made changes to further support our metabolic focus by adding expertise to our Board of Directors and forming a clinical and scientific advisory board with key opinion leaders. We believe that our uplisting to NASDAQ and strong cash position provide us with the foundation to efficiently execute our Phase 2 obesity clinical trial and build on our strategic vision."

Key Corporate and Clinical Program Highlights

Phase 2 Trial in Obesity Expected to Begin in Q3 2024

Nimacimab, is a first-in-class humanized monoclonal antibody that acts as a negative allosteric modulator to inhibit CB1 signaling in the periphery.

- Skye recently announced its *CBeyond*™ Phase 2 clinical trial design for nimacimab, for the treatment of obesity. This 120-patient trial is on track to begin screening in Q3 2024 and is expected to provide interim and topline data in Q2 and Q4 of 2025, respectively. The trial's primary endpoint is to evaluate weight loss using nimacimab compared to placebo.
- Secondary endpoints include evaluations of safety and tolerability, neuropsychiatric and cognitive evaluation, change in body composition by Dual-Energy X-ray Absorptiometry (DEXA), and changes in key metabolic biomarkers such as triglycerides, insulin and leptin sensitivity.
- This trial will also be the first to evaluate the combination of a CB1 inhibitor (nimacimab) and a GLP-1 agonist (Wegovy®) in humans in an exploratory arm which

will assess the difference in weight loss, the difference in body composition and changes in sleep quality.

- In connection with the Company's *CBeyond*™ trial for nimacimab, Skye announced a collaboration with Beacon Biosignals. Because obesity is recognized as detrimentally affecting sleep quality in some people[1], Skye's *CBeyond*™ trial will use Beacon Biosignal's FDA 510(k)-cleared Dreem Headband to collect sleep data and assess validated sleep endpoints in a subset of 40 patients, encompassing all arms of the trial, as an exploratory endpoint.

Completion of Glaucoma Study

- Skye completed a Phase 2a double-masked randomized, placebo-controlled trial of SBI-100 Ophthalmic Emulsion ("SBI-100 OE") in 56 patients with elevated intraocular pressure (IOP) diagnosed with primary open-angle glaucoma or ocular hypertension. The primary endpoint evaluated the change in diurnal IOP in the treated arm vs. placebo over 2 weeks. The study did not achieve a statistically significant improvement in IOP over placebo.

- Skye has discontinued all clinical development, and research and development related to SBI-100 OE, including its ophthalmology pipeline, and redirected capital resources from its ocular program to its metabolic program.

Corporate Highlights

- Skye recently announced the appointment of Karen Smith, MD, Ph.D., MBA, LLM, to its Board of Directors. Dr. Smith brings significant global biotech and biopharma leadership expertise to Skye, including over 10 years of board and advisory experience.
- Skye recently announced the appointment of a new Clinical and Scientific Advisory Board to support the development of nimacimab, with advisors including Lee Kaplan, MD, Ph.D., Louis Aronne, MD, Rekha Kumar, MD, M.S., Marcus DaSilva Goncalves, MD, Ph.D., Beverly Tchang, MD, Eduardo Muñoz, MD, Ph.D. and Giovanni Appendino, Ph.D.
- Skye uplisted to the NASDAQ Global Market® stock exchange from the OTCQB.
- Skye was included in the Russell 2000® Index and the broad-market Russell 3000® Index, effective at the U.S. market open on July 1, 2024, as part of the annual reconstitution of the Russell stock indexes.
- Subsequent to the end of second quarter, in August, Skye's convertible debt with a principal balance of $5.0 million was converted into 968,973 shares of the Company's common stock.

Second Quarter 2024 Financial Highlights:

Cash Position: Cash and cash equivalents totaled $74.1 million, excluding restricted cash of $9.1 million on June 30, 2024. The Company expects its current cash and cash equivalents to fund projected operations through at least the first half of 2027.

R&D Expenses: Research and development (R&D) expenses for the second quarter of 2024 were $4.1 million, as compared to $1.8 million for the same period in 2023. The increase was primarily due to costs associated with the completion of our Phase 2a clinical trial for glaucoma, which has since been discontinued, and the costs from the preparation of the launch of our Phase 2 clinical trial for the treatment of obesity.

G&A Expenses: General and administrative (G&A) expenses for the second quarter of 2024 were $4.3 million, as compared to $1.2 million for the same period in 2023. The increase was primarily due to increases in non-cash incentive stock-based compensation, professional services and fees associated with the Company's January and March 2024 PIPE financings, uplisting to NASDAQ and expansion to support and advance its operations as a publicly-traded company.

Net Loss: Net loss for the second quarter of 2024 totaled $7.9 million, with non-cash share-based compensation expense of $1.8 million and non-cash interest expense of $0.3 million, compared to $3.1 million for the second quarter of 2023 with non-cash share-based compensation expense of $0.1 million.

1 Shazia Jehan et al, "Obstructive Sleep Apnea and Obesity: Implications for Public Health," Sleep Med Disord. 2017; 1(4): 00019. Published online 2017 Dec 12.

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 plans to start a Phase 2 clinical trial in obesity in Q3 2024 for nimacimab, a negative allosteric modulating antibody that peripherally inhibits CB1, comparing monotherapy and combination arms of nimacimab and a GLP-1R agonist (Wegovy®). For more information, please visit: https://www.skyebioscience.com. Connect with us on Twitter 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, business strategy, the timing of clinical trials for nimacimab, the therapeutic potential of nimacimab 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 June 30,		For the Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses				
Research and development	$ 4,078,751	$ 1,788,434	$ 6,025,201	$ 2,973,314
General and administrative	4,326,820	1,206,405	8,532,620	3,121,683
Estimated legal contingency	—	(151,842)	—	(151,842)
Total operating expenses	8,405,571	2,842,997	14,557,821	5,943,155
Operating loss	(8,405,571)	(2,842,997)	(14,557,821)	(5,943,155)
Other (income) expense				
Interest expense	450,052	186,429	886,988	204,828
Interest income	(961,237)	(8,598)	(1,388,791)	(33,112)
(Gain) loss from asset sales	—	—	(1,145,141)	307,086
Debt conversion inducement expense	—	—	—	1,383,285
Wind-down costs	—	87,072	—	470,181
Other expense (income)	359	—	1,399	(3)
Total other (income) expense, net	(510,826)	264,903	(1,645,545)	2,332,265
Loss before income taxes	(7,894,745)	(3,107,900)	(12,912,276)	(8,275,420)
Provision for income taxes	8,071	3,600	10,071	3,600
Net loss	$ (7,902,816)	$(3,111,500)	$(12,922,347)	$(8,279,020)
Loss per common share:				
Basic	$ (0.20)	$ (0.80)	$ (0.39)	$ (2.16)

Diluted	$ (0.20)	$ (0.80)	$ (0.39)	$ (2.16)
Weighted average shares of common stock outstanding used to compute earnings per share:				
Basic	38,669,330	3,886,198	33,334,616	3,827,216
Diluted	38,669,330	3,886,198	33,334,616	3,827,216

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

	June 30, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 74,120,854	$ 1,256,453
Restricted cash	9,080,202	9,080,202
Prepaid expenses	1,096,039	194,259
Other current assets	2,707,368	1,119,929
Total current assets	87,004,463	11,650,843
Property and equipment, net	45,772	43,276
Operating lease right-of-use asset	202,987	237,983
Other assets	8,309	8,309
Total assets	$ 87,261,531	$ 11,940,411
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 1,079,493	$ 1,155,785
Accrued interest - related party	124,658	126,027
Accrued payroll liabilities	556,573	888,381
Accrued interest - legal contingency	384,896	234,750
Other current liabilities	1,184,795	998,552
Estimate for legal contingency	6,053,468	6,053,468
Convertible note - related party, net of discount	4,859,525	4,371,998
Operating lease liability, current portion	79,165	72,038
Total current liabilities	14,322,573	13,900,999
Non-current liabilities		
Operating lease liability, net of current portion	129,907	171,230

Total liabilities	14,452,480	14,072,229
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit)		
Preferred stock, $0.001 par value; 200,000 shares authorized at June 30, 2024 and December 31, 2023; no shares issued and outstanding at June 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at June 30, 2024 and December 31, 2023; 28,067,907 and 12,349,243 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	28,068	12,349
Additional paid-in-capital	190,085,879	102,238,382
Accumulated deficit	(117,304,896)	(104,382,549)
Total stockholders' equity (deficit)	72,809,051	(2,131,818)
Total liabilities and stockholders' equity (deficit)	$ 87,261,531	$ 11,940,411

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