Lipocine Announces Financial Results for the First Quarter Ended March 31, 2023

SALT LAKE CITY, May 11, 2023 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on treating Central Nervous System (CNS) disorders by leveraging its proprietary platform to develop differentiated products, today announced financial results for the first quarter ended March 31, 2023, and provided a corporate update.

First Quarter Highlights

Neuroactive Steroid for Depression

Dosing was initiated in a pilot clinical bridge study of LPCN 1154 (oral brexanolone) a neuroactive steroid product candidate that Lipocine is developing for postpartum depression ("PPD"). LPCN 1154 is targeted to be a differentiated oral treatment option as a mono or add-on therapy for patients with unresolved symptoms needing fast onset with high response in short treatment duration.

- Results are expected in the second quarter of the year. The FDA has agreed with Lipocine's proposal for establishing the efficacy of LPCN 1154 via the 505(b)(2) pathway. The proof-of-concept study is a prelude to a single confirmatory Pivotal PK study in place of an efficacy study for NDA submission.

LPCN 1148 in liver cirrhosis

LPCN 1148 is being evaluated in an ongoing Phase 2 proof-of-concept ("POC") study for the management of decompensated cirrhosis of various etiologies. Topline results are expected mid-2023.

Lipocine continues to explore partnering opportunities for LPCN 1107, our candidate for prevention of preterm birth, LPCN 1148, for the management of decompensated cirrhosis, LPCN 1144, our candidate for treatment of non-cirrhotic NASH, and LPCN 1111, a once-a-day therapy candidate for testosterone replacement therapy (TRT).

Quarter Ended March 31, 2023 Financial Results

Lipocine reported a net loss of $3.9 million, or ($0.04) per diluted share, for the three months ended March 31, 2023, compared with a net loss of $3.5 million or ($0.04) per diluted share, in the three months ended March 31, 2022.

Lipocine recognized license revenue for payments receivable from Spriaso under a licensing agreement in the cough and cold field of approximately $55,000 during the three months ended March 31, 2023. There was no revenue during the three months ended March 31, 2022.

Research and development expenses were $3.1 million and $1.9 million, respectively, for the three months ended March 31, 2023, and 2022. The increase in research and development expenses year-over-year was the result of an increase in contract research organization expense related to the Phase 2 POC study with LPCN 1148, an increase in costs related to LPCN 1154 clinical studies, an increase in personnel costs and expenses related to lab supplies, small equipment and other research and development costs. These increases were offset by a decrease in LPCN 1111 scale up costs, a decrease in contract research organization expense and outside consulting costs related to the completion of the LPCN 1144 LiFT Phase 2 clinical study, and a decrease in expenses as a result of completing the PK and food effect studies for LPCN 1154 and LPCN 1107 in 2022.

General and administrative expenses were $1.3 million and $1.2 million, respectively, for the three months ended March 31, 2023, and 2022. The increase in general and administrative expenses year-over-year was primarily due to increases in corporate legal fees, business development consulting fees, director fees, and various professional fees. These were offset by decreases in corporate insurance expense and general and administrative expenses.

As of March 31, 2023, Lipocine had $28.9 million of unrestricted cash, cash equivalents and marketable investment securities compared to $32.5 million at December 31, 2022.

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery to develop products for CNS disorders. Lipocine has candidates in development as well as candidates for which we are exploring partnering. Our candidates represent the enablement of patient friendly oral delivery options for a favorable benefit to risk profile which target large addressable markets with significant unmet medical needs.

Lipocine clinical development candidates include: LPCN 1154, oral brexanolone, for the potential treatment of

postpartum depression, LPCN 2101 for the potential treatment of epilepsy and LPCN 1148, an oral prodrug of bioidentical testosterone targeted for the management of symptoms associated with liver cirrhosis. Lipocine is exploring partnering opportunities for LPCN 1107, our candidate for prevention of preterm birth, LPCN 1148, for the management of decompensated cirrhosis, LPCN 1144, our candidate for treatment of non-cirrhotic NASH, and LPCN 1111, a once-a-day therapy candidate for testosterone replacement therapy (TRT). TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate developed by Lipocine, is approved by the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. For more information, please visit www.lipocine.com.

Forward-Looking Statements

This release contains "forward-looking statements" that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and include statements that are not historical facts regarding our product development efforts, our strategic plans for developing products to treat CNS disorders, our ability to monetize non-core product candidates, the application of our proprietary platform in developing new treatments for CNS disorders, our product candidates and related clinical trials, the achievement of milestones within and completion of clinical trials, the timing and completion of regulatory reviews, outcomes of clinical trials of our product candidates, and the potential uses and benefits of our product candidates. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that we may not be successful in developing product candidates to treat CNS disorders, we may not be able to enter into partnerships or other strategic relationships to monetize our non-core assets, the FDA will not approve any of our products, risks related to our products, expected product benefits not being realized, clinical and regulatory expectations and plans not being realized, new regulatory developments and requirements, risks related to the FDA approval process including the receipt of regulatory approvals, the results and timing of clinical trials, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine's products, and other risks detailed in Lipocine's filings with the SEC, including, without limitation, its Form 10-K and other reports on Forms 8-K and 10-Q, all of which can be obtained on the SEC website at www.sec.gov. Lipocine assumes no obligation to update or revise publicly any forward-looking statements contained in this release, except as required by law.

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

(Unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 4,769,180	$ 3,148,496
Marketable investment securities	24,100,430	29,381,410
Accrued interest income	39,060	80,427
Contract asset - current portion	579,428	579,428
Prepaid and other current assets	1,126,731	945,319
Total current assets	30,614,829	34,135,080
Contract asset - non-current portion	3,252,500	3,252,500
Property and equipment, net of accumulated depreciation of $1,158,349 and $1,153,530 respectively	130,770	131,589
Other assets	23,753	23,753
Total assets	$ 34,021,852	$ 37,542,922
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 796,476	$ 600,388
Accrued expenses	1,133,626	1,077,738
Total current liabilities	1,930,102	1,678,126
Warrant liability	131,722	229,856

Total liabilities	2,061,824	1,907,982
Commitments and contingencies		
Mezzanine equity:		
Preferred stock, par value $0.0001 per share ($0.001 per share redemption value), 10,000,000 shares authorized; 88,511 and zero issued and outstanding at March 31, 2023 and December 31, 2022, respectively	9	-
Stockholders' equity:		
Common stock, par value $0.0001 per share, 200,000,000 shares authorized; 88,516,501 issued and 88,510,791 outstanding	8,852	8,852
Additional paid-in capital	219,284,000	219,112,164
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	3,241	(20,321)
Accumulated deficit	(187,295,362)	(183,425,043)
Total stockholders' equity	31,960,028	35,634,940
Total liabilities and stockholders' equity	$ 34,021,852	$ 37,542,922

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Revenues:	$ 54,990	$ -
Operating expenses:		
Research and development	3,106,310	1,887,953
General and administrative	1,287,313	1,243,687
Total operating expenses	4,393,623	3,131,640
Operating loss	(4,338,633)	(3,131,640)
Other income (expense):		
Interest and investment income	370,469	41,576
Interest expense	-	(19,529)
Unrealized gain (loss) on warrant liability	98,134	(377,988)
Total other income (expense), net	468,603	(355,941)
Loss before income tax expense	(3,870,030)	(3,487,581)
Income tax expense	(200)	(200)
Net loss	(3,870,230)	(3,487,781)
Issuance of Series B preferred stock dividend	(89)	-
Net loss attributable to common shareholders	$(3,870,319)	$(3,487,781)
Basic loss per share attributable to common stock	$ (0.04)	$ (0.04)
Weighted average common shares outstanding, basic	88,510,791	88,309,628

Diluted loss per share attributable to common stock	$ (0.04)	$ (0.04)
Weighted average common shares outstanding, diluted	88,510,791	88,309,628
Comprehensive loss:		
Net loss	$(3,870,319)	$(3,487,781)
Net unrealized gain (loss) on available-for-sale securities	23,562	(49,400)
Comprehensive loss	$(3,846,757)	$(3,537,181)

SOURCE Lipocine Inc.

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