

Lipocine Announces Financial Results for the Second Quarter Ended June 30, 2023

SALT LAKE CITY, Aug. 10, 2023 [/PRNewswire/](#) -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on treating Central Nervous System (CNS) disorders, today announced financial results for the second quarter and six months ended June 30, 2023, and provided a corporate update.

Clinical Program Highlights

Neuroactive Steroids

- Lipocine announced positive topline results from a pilot pharmacokinetics ("PK") bridge study of LPCN 1154 (oral brexanolone). Lipocine is developing LPCN 1154 for postpartum depression ("PPD")
 - The bridge study results demonstrated comparative pharmacokinetics of LPCN 1154 to an approved IV brexanolone
 - The study identified a dosing regimen of LPCN 1154 to be tested in a single confirmatory pivotal PK study required for NDA filing
 - LPCN 1154 treatment was well-tolerated with no hypoxia or sedation-related adverse events

LPCN 1148 in liver cirrhosis

- Lipocine announced positive topline results from its Phase 2 proof-of-concept ("POC") study evaluating LPCN 1148 in cirrhosis
 - Study met primary endpoint: treatment with LPCN 1148 increased L3 skeletal muscle index (L3-SMI) relative to placebo (P < 0.01)
 - Fewer hepatic encephalopathy (HE) events of grade >1 in the LPCN 1148 treatment arm relative to placebo (P < 0.05)
 - More patients on LPCN 1148 reported symptom improvement compared to placebo (P < 0.05)
 - LPCN 1148 was well-tolerated, with AE rates and severities similar to placebo
 - Lipocine plans to meet with the FDA to discuss the development path to NDA filing
- Posters on LPCN 1148 and LPCN 1144 were presented at the [European Association for the Study of the Liver \(EASL\) Congress 2023](#), in Vienna, Austria, June 21 – 24, 2023

Quarter Ended June 30, 2023 Financial Results

Lipocine reported a net loss of \$3.6 million, or (\$0.68) per diluted share, for the three months ended June 30, 2023, compared with a net loss of \$2.6 million or (\$0.61) per diluted share, in the three months ended June 30, 2022.

Lipocine did not recognize any revenue during the three months ended June 30, 2023. During the three months ended June 30, 2022, we recognized revenue related to a non-refundable cash fee of \$0.5 million received from Antares for consideration of a 90-day extension for Antares to exercise its option to license LPCN 1111.

Research and development expenses were \$2.5 million and \$2.9 million, respectively, for the three months ended June 30, 2023, and 2022. The decrease in research and development expenses year over year was a result of a decrease in costs related to our LPCN 1154 clinical studies, a decrease in lab supplies, small equipment and other research and development costs, a decrease in contract research organization expense and outside consulting costs related to the completion of our LPCN 1144 LiFT study in 2022, a decrease related to our completed PK and food effect studies for LPCN 1107, and a decrease in LPCN 1111 scale up costs. These decreases were offset by an increase in contract research organization expense related to the LPCN 1148 Phase 2 POC study in male subjects with cirrhosis, an increase in personnel related costs and an increase in TLANDO related costs.

General and administrative expenses were \$1.4 million and \$1.1 million, respectively, for the three months ended June 30, 2023, and 2022. The increase in general and administrative expenses year over year was primarily due to an increase in professional and legal fees related to our reverse stock split and other general and administrative expenses, an increase in estimated franchise taxes resulting from our reverse stock split, as well as increases in business development fees, personnel salaries and benefits, market research activities and director fees. These increases were offset by a decrease resulting from professional fees incurred in our recruitment of two additional directors in 2022 and a decrease in corporate insurance expense.

As of June 30, 2023, Lipocine had \$25.8 million of unrestricted cash, cash equivalents and marketable investment securities compared to \$32.5 million at December 31, 2022.

Six Months Ended June 30, 2023 Financial Results

Lipocine reported a net loss of \$7.4 million, or (\$1.44) per diluted share, for the six months ended June 30, 2023, compared with a net loss of \$6.1 million or (\$1.20) per diluted share, in the six months ended June 30, 2022.

Lipocine recognized license revenue of approximately \$55,000 during the six months ended June 30, 2023. We recognized revenue related to a non-refundable cash fee of \$0.5 million received from Antares for consideration of a 90-day extension for Antares to exercise its option to license LPCN 1111 during the six months ended June 30, 2022.

Research and development expenses were \$5.6 million and \$4.8 million, respectively, for the six months ended June 30, 2023, and 2022. The increase in research and development expenses year over year resulted from an increase in contract research organization expense related to the Phase 2 POC study of LPCN 1148, an increase in costs related to LPCN 1154 clinical studies, an increase in personnel salaries and benefits resulting from the hiring of additional personnel, and an increase in TLANDO related expenses. These increases were offset by a decrease in contract research organization expense and outside consulting costs related to the completion of our LPCN 1144 LiFT study 2022, a decrease related to LPCN 1111 scale up costs in 2022, a decrease related to the completion of our LPCN 1107 PK and food effect studies in 2022 and a decrease in expenses for lab supplies, small equipment and other research and development activities.

General and administrative expenses were \$2.7 million and \$2.4 million, respectively, for the six months ended June 30, 2023, and 2022. The increase in general and administrative expenses year over year was primarily due to an increase in professional and legal fees related to our reverse stock split and other general and administrative expenses, an increase in business development fees, an increase in estimated franchise taxes, an increase in director fees, an increase in personnel salaries and benefit costs, and an increase in market research activities. These increases were offset by a decrease resulting from professional fees incurred in our recruitment of two additional directors in 2022 and a decrease in corporate insurance expense.

For more information on Lipocine's financial results for the three and six months ended June 30, 2023, refer to Form 10Q filed with the SEC.

About Lipocine

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

Lipocine's 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, a novel androgen receptor agonist prodrug for oral administration 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 1154, for rapid relief of postpartum depression, 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, the application of our proprietary platform in developing new treatments for CNS disorders, our product candidates and related clinical trials, our development of and filing of a NDA with the FDA for LPCN 1148, 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 have sufficient capital to complete the development processes for our product candidates, 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 and our ability to utilize a streamlined approval pathway for LPCN 1154, 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)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,014,695	\$ 3,148,496
Marketable investment securities	20,775,275	29,381,410
Accrued interest income	24,230	80,427
Contract asset - current portion	579,428	579,428
Prepaid and other current assets	690,900	945,319
Total current assets	<u>27,084,528</u>	<u>34,135,080</u>

Contract asset - non-current portion	3,252,500	3,252,500
Property and equipment, net of accumulated depreciation of \$1,166,441 and \$1,153,530 respectively	122,679	131,589
Other assets	23,753	23,753
Total assets	<u>\$ 30,483,460</u>	<u>\$ 37,542,922</u>

Liabilities and Stockholders' Equity

Current liabilities:		
Accounts payable	\$ 517,587	\$ 600,388
Accrued expenses	1,309,595	1,077,738
Total current liabilities	<u>1,827,182</u>	<u>1,678,126</u>
Warrant liability	104,267	229,856
Total liabilities	<u>1,931,449</u>	<u>1,907,982</u>

Commitments and contingencies

Stockholders' equity:

Common stock, par value \$0.0001 per share, 200,000,000
shares authorized; 5,235,166 issued and 5,234,830

outstanding	8,852	8,852
Additional paid-in capital	219,443,674	219,112,164
Treasury stock at cost, 336 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(15,812)	(20,321)
Accumulated deficit	(190,843,991)	(183,425,043)
Total stockholders' equity	<u>28,552,011</u>	<u>35,634,940</u>

Total liabilities and stockholders' equity	<u>\$ 30,483,460</u>	<u>\$ 37,542,922</u>
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LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:	\$ -	\$ 500,000	\$ 54,990	\$ 500,000
Operating expenses:				
Research and development	2,515,211	2,898,012	5,621,521	4,785,965
General and administrative	1,440,394	1,129,519	2,727,708	2,373,205
Total operating expenses	<u>3,955,605</u>	<u>4,027,531</u>	<u>8,349,229</u>	<u>7,159,170</u>
Operating loss	<u>(3,955,605)</u>	<u>(3,527,531)</u>	<u>(8,294,239)</u>	<u>(6,659,170)</u>
Other income (expense):				
Interest and investment income	379,521	69,877	749,991	111,453
Interest expense	-	(7,568)	-	(27,098)
Unrealized gain on warrant liability	27,455	583,445	125,589	205,457
Gain on litigation settlement liability	-	250,000	-	250,000
Total other income, net	<u>406,976</u>	<u>895,754</u>	<u>875,580</u>	<u>539,812</u>
Loss before income tax expense	<u>(3,548,629)</u>	<u>(2,631,777)</u>	<u>(7,418,659)</u>	<u>(6,119,358)</u>
Income tax expense	-	-	(200)	(200)
Net loss	<u>(3,548,629)</u>	<u>(2,631,777)</u>	<u>(7,418,859)</u>	<u>(6,119,558)</u>
Issuance of Series B preferred stock dividend	-	-	(89)	-
Net loss attributable to common shareholders	<u>\$ (3,548,629)</u>	<u>\$ (2,631,777)</u>	<u>\$ (7,418,948)</u>	<u>\$ (6,119,558)</u>

Basic loss per share attributable to common stock	\$ (0.68)	\$ (0.50)	\$ (1.42)	\$ (1.17)
Weighted average common shares outstanding, basic	5,234,830	5,234,141	5,234,830	5,228,608
Diluted loss per share attributable to common stock	\$ (0.68)	\$ (0.61)	\$ (1.44)	\$ (1.20)
Weighted average common shares outstanding, diluted	5,234,830	5,263,389	5,234,830	5,262,993
Comprehensive loss:				
Net loss	\$ (3,548,629)	\$ (2,631,777)	\$ (7,418,859)	\$ (6,119,558)
Net unrealized gain (loss) on available-for-sale securities	(19,053)	(17,491)	4,509	(66,891)
Comprehensive loss	\$ (3,567,682)	\$ (2,649,268)	\$ (7,414,350)	\$ (6,186,449)

SOURCE Lipocine Inc.

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<https://ir.lipocine.com/2023-08-10-Lipocine-Announces-Financial-Results-for-the-Second-Quarter-Ended-June-30,-2023>