Lipocine Announces Financial Results for the Third Quarter Ended September 30, 2023

SALT LAKE CITY, Nov. 8, 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 third quarter and nine months ended September 30, 2023, and provided a corporate update.

Clinical Program Highlights

Neuroactive Steroids

- On October 18, Lipocine completed a successful meeting with the FDA on LPCN 1154, which is in development for postpartum depression (PPD). The FDA agreed on Lipocone's proposal for a 505(b)(2) NDA filing based on a single pivotal study comparing exposure of LPCN 1154 with the approved IV infusion of brexanolone
    - Lipocine anticipates initiating the pivotal study program in Q1 2024 with the LPCN 1154 "to be marketed" formulation
    - Top line results from the study are expected by Q2 2024, with a goal of filing a New Drug Application (NDA) in 2024
    - If approved, LPCN 1154, has the potential to be a differentiated preferred treatment option for PPD with rapid and high remission/response rates with short treatment duration

LPCN 1148 in liver cirrhosis

- In July, 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

Quarter Ended September 30, 2023 Financial Results

Lipocine reported a net loss of $6.7 million, or ($1.27) per diluted share, for the three months ended September 30, 2023, compared with a net loss of $2.4 million or ($0.52) per diluted share, in the three months ended September 30, 2022.

During the three months ended September 30, 2023, the Company recognized a non-cash minimum guaranteed royalties revenue reversal of variable consideration revenue of $3.1 million related to the termination of the Antares License Agreement. The reversal of revenue is due to the fact that Lipoocine will not receive anticipated royalties that were previously recorded for the Antares License Agreement due to the termination of the agreement.

Research and development expenses were $2.9 million during the three months ended September 30, 2023, as compared with $2.1 million in the three months ended September 30, 2022. The increase in research and development expenses was a result of an increase in costs related to the LPCN 1154 clinical studies, an increase in TLANDO manufacturing related costs, and an increase in personnel related costs, offset by a decrease in LPCN 1111 scale up costs in 2022, a decrease in contract research organization expense related to the LPCN 1148 Phase 2 POC study in male subjects with cirrhosis, a decrease in contract research organization expense and outside consulting costs related to the completion of the LPCN 1144 LiFT study in 2022, and a decrease in LPCN 1107 PK and food effect studies and other research and development costs in 2022.

General and administrative expenses were $1.0 million during the three months ended September 30, 2023, as compared to $0.8 million in the three months ended September 30, 2022. The increase in expenses is mainly due to increases in business development expenses, and an increase in professional services and legal fees. These increases were offset by a decrease in corporate insurance expense.

As of September 30, 2023, Lipocine had $23.8 million of unrestricted cash, cash equivalents and marketable investment securities compared to $32.5 million at December 31, 2022.

Nine Months Ended September 30, 2023 Financial Results

Lipocine reported a net loss of $14.1 million, or ($2.72) per diluted share, for the nine months ended September 30, 2023, compared with a net loss of $8.5 million or ($1.72) per diluted share, in the nine months ended September 30, 2022.

The Company recognized a non-cash minimum guaranteed royalties revenue reversal of variable consideration revenue of $3.1 million related to the termination of the Antares License Agreement during the nine months ended September 30, 2023. The reversal of variable consideration revenue is offset by license revenue of approximately $55,000 for payments received from Spriaso, a related party, under a licensing agreement for the cough and cold field during the nine months ended September 30, 2023. The Company recognized revenue related to a non-refundable cash fee of $500,000 received from Antares for consideration of a 90-day extension for Antares to exercise its option to license LPCN 1111 during the nine months ended September 30, 2022.

Research and development expenses were $8.5 million and $6.9 million, respectively, for the nine months ended September 30, 2023, and 2022. The increase was due to an increase in costs related to the LPCN 1154 clinical studies, an increase in TLANDO manufacturing related costs, an increase in contract research organization expense related to the LPCN 1148 Phase 2 POC study in male subjects with cirrhosis, and an increase in personnel salaries and benefits. These increases were offset by a decrease related to LPCN 1111 scale up costs in 2022, a decrease in contract research organization expense and outside consulting costs related to the completion of our LPCN 1144 LiFT study, a decrease related to the completion of our LPCN 1107 PK and food effect studies and a decrease in other research and development activities.

General and administrative expenses were $3.8 million and $3.2 million, respectively, for the nine months ended September 30, 2023, and 2022. The increase consisted of an increase in business development expenses, an increase in professional and legal fees and an increase in other general and administrative expenses. These increases were offset by decrease resulting from a decrease in corporate insurance expense and a decrease in various other consulting fees.

For more information on Lipocine's financial results for the three and nine months ended September 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 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, LPCN1154, 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, our strategic plans for developing products to treat CNS disorders, our ability to monetize non-core product candidates, including through entering into partnering arrangements, 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)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 4,072,706	$ 3,148,496
Marketable investment securities	19,775,290	29,381,410
Accrued interest income	41,061	80,427
Contract asset - current portion	130,505	579,428
Prepaid and other current assets	594,097	945,319
Total current assets	24,613,659	34,135,080
Contract asset - non-current portion	-	3,252,500
Property and equipment, net of accumulated depreciation of $1,174,189 and $1,153,530 respectively	114,931	131,589
Other assets	23,753	23,753
Total assets	$ 24,752,343	$ 37,542,922
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,101,068	$ 600,388
Accrued expenses	1,140,313	1,077,738
Total current liabilities	2,241,381	1,678,126
Warrant liability	29,440	229,856
Total liabilities	2,270,821	1,907,982
Stockholders' equity:		
Common stock, par value $0.0001 per share, 200,000,000 shares authorized; 5,316,166 and 5,235,166 issued and 5,315,830 and 5,234,830 outstanding	8,860	8,852
Additional paid-in capital	220,022,838	219,112,164
Treasury stock at cost, 336 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(14,503)	(20,321)
Accumulated deficit	(197,494,961)	(183,425,043)
Total stockholders' equity	22,481,522	35,634,940
Total liabilities and stockholders' equity	$ 24,752,343	$ 37,542,922

LIPOCINE INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
License revenue	$ -	$ -	$ 54,990	$ 500,000
Minimum guaranteed royalties revenue (reversal of variable consideration)	(3,121,996)	-	(3,121,996)	-
Total revenues (reversal of variable consideration), net	(3,121,996)	-	(3,067,006)	500,000
Operating expenses:				
Research and development	2,878,798	2,100,432	8,500,319	6,886,398
General and administrative	1,042,572	798,939	3,770,281	3,172,144
Total operating expenses	3,921,370	2,899,371	12,270,600	10,058,542
Operating loss	(7,043,366)	(2,899,371)	(15,337,606)	(9,558,542)
Other income (expense):				
Interest and investment income	317,569	163,966	1,067,561	275,420
Interest expense	-	-	-	(27,098)
Unrealized gain on warrant liability	74,827	326,240	200,416	531,697
Gain on litigation settlement liability	-	-	-	250,000
Total other income, net	392,396	490,206	1,267,977	1,030,019
Loss before income tax expense	(6,650,970)	(2,409,165)	(14,069,629)	(8,528,523)
Income tax expense	-	-	(200)	(200)
Net loss	(6,650,970)	(2,409,165)	(14,069,829)	(8,528,723)
Issuance of Series B preferred stock dividend	-	-	(89)	-
Net loss attributable to common shareholders	$ (6,650,970)	$ (2,409,165)	$ (14,069,918)	$ (8,528,723)
Basic loss per share attributable to common stock	$ (1.26)	$ (0.46)	$ (2.68)	$ (1.63)
Weighted average common shares outstanding, basic	5,292,058	5,234,576	5,254,116	5,230,619
Diluted loss per share attributable to common stock	$ (1.27)	$ (0.52)	$ (2.72)	$ (1.72)
Weighted average common shares outstanding, diluted	5,292,058	5,250,179	5,254,116	5,260,530
Comprehensive loss:				
Net loss	$ (6,650,970)	$ (2,409,165)	$ (14,069,829)	$ (8,528,723)
Net unrealized gain (loss) on available-for-sale securities	1,309	7,972	5,818	(58,919)
Comprehensive loss	$ (6,649,661)	$ (2,401,193)	$ (14,064,011)	$ (8,587,642)

SOURCE Lipocine Inc.

For further information: For further information: Krista Fogarty, Phone: (801) 994-7383, kf@lipocine.com; Investors: PJ Kelleher, Phone: (617) 430-7579, pkelleher@lifesciadvisors.com