

Lipocine Announces Financial Results for the Third Quarter Ended September 30, 2022

SALT LAKE CITY, Nov. 9, 2022 [/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, 2022 and provided a corporate update.

"During the third quarter we announced a new strategic direction for Lipocine, which involves applying our validated technology to develop differentiated treatments for CNS disorders. Our initial focus is on endogenous neuroactive steroids which have broad applicability in treating various CNS conditions," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "Our most advanced neuroactive steroid ("NAS") candidate is LPCN 1154, which we are developing for the treatment of postpartum depression. We recently initiated a pilot PK bridge study (a prelude to a pivotal study required for NDA filing) and look forward to reporting results of the pilot study in the first half of 2023."

Third Quarter Highlights

Strategic realignment and focus on CNS

- In September, Lipocine announced a strategic realignment and forward focus on treating CNS disorders. The Company's initial focus is to advance its pipeline of endogenous neuroactive steroids ("NAS") which have potential to treat various neuropsychiatric conditions.
- Lipocine's CNS development portfolio includes LPCN 1154, a fast-acting oral antidepressant for postpartum depression ("PPD") with potential for outpatient use; LPCN 2101, with a novel mechanism of action, for women with epilepsy; and additional undisclosed CNS focused candidates.
- The Company is exploring partnering its portfolio of non-core assets (LPCN 1144 for treatment of non-cirrhotic NASH, LPCN 1148 for decompensated liver cirrhosis, LPCN 1107 for prevention of pre-term birth, and LPCN 1111, a once-a-day therapy for TRT), consistent with our strategy designed to diversify risk and potentially create opportunities for non-dilutive financing.

Corporate

- Appointed Spyros Papapetropoulos, M.D. Ph.D., as Lead Director and Chairman of the Board. Dr. Papapetropoulos has served on Lipocine's board since April 2022.
- Appointed George Nomikos, M.D., Ph.D., as Chief Medical Officer. Dr. Nomikos is an R&D scientist and psychiatry-trained clinician with extensive academic and industry experience in neuropsychiatric, neurometabolic, neurohormonal, neuromuscular and chronic pain therapeutics.

Third quarter Ended September 30, 2022 Financial Results

Lipocine reported a net loss of \$2.4 million, or (\$0.03) per diluted share for the quarter ended September 30, 2022, compared with a net loss of \$3.1 million, or (\$0.04) per diluted share, in the quarter ended September 30, 2021.

There were no revenues in the quarter ended September 30, 2022. There was \$55,000 in license revenue recorded in the quarter ended September 30, 2021 related to payments received from Spriaso under a licensing agreement which did not recur in 2022.

Research and development expenses were \$2.1 million for the quarter ended September 30, 2022, compared with \$2.4 million for the quarter ended September 30, 2021. The decrease in research and development expenses was primarily due to a decrease in expenses related to the LPCN 1154 clinical studies, a decrease in expenses and consulting costs related to the completion of the LPCN 1144 LiFT Phase 2 clinical study in NASH subjects, and a decrease in costs associated with TLANDO. These decreases were offset by an increase in costs related to the Phase 2 POC study in male cirrhotic subjects with LPCN 1148, an increase in LPCN 1111 manufacturing scale up, an increase in LPCN 1107 clinical studies, and an increase in other research and development costs and personnel expenses.

General and administrative expenses were \$0.8 million for the quarter ended September 30, 2022, compared with \$1.2 million for the quarter ended September 30, 2021. The decrease in general and administrative expenses was primarily due to decreases in legal expenses, personnel costs, corporate insurance expense and other G&A expenses. The decreases were offset by an increase in directors' fees resulting from the addition of two new directors, increases in professional and consulting fees and increases in travel related expense.

As of September 30, 2022, the company had \$34.3 million of unrestricted cash, cash equivalents and marketable investment securities, compared to \$46.6 million on December 31, 2021.

Nine Months Ended September 30, 2022 Financial Results

Lipocine reported a net loss of \$8.5 million, or (\$0.10) per diluted share, for the nine months ended September 30, 2022, compared with a net loss of \$13.3 million, or (\$0.16) per diluted share, in the nine months ended September 30, 2021.

Revenues in the nine months ended September 30, 2022 were \$0.5 million, compared with revenues of \$55,000 in the comparable period in 2021. The increase in revenue was primarily related to a non-refundable cash fee received from Antares for consideration of a 90 day extension to exercise its option to license LPCN 1111.

Research and development expenses for the nine months ended September 30, 2022, were \$6.9 million compared to \$5.4 million for the comparable period in 2021. The increase in research and development expenses was due to an increase in expenses related to the Phase 2 POC study in male cirrhotic subjects with LPCN 1148, an increase in costs related to LPCN 1154 clinical studies, an increase in expenses related to LPCN 1111 scale up activities and a food effect study in LPCN 1107, an increase in personnel expense and other research and development costs. These increases were offset by a decrease in expenses related to the completion of the LPCN 1144 LiFT Phase 2 clinical study in NASH subjects, and a decrease in costs associated with TLANDO.

General and administrative expenses for the nine months ended September 30, 2022 were \$3.2 million compared to \$4.3 million for the comparable period in 2021. The decrease in general and administrative expenses was primarily due to a decrease in legal fees, a decrease in personnel costs and a decrease in other general and administrative expenses. These decreases were offset by an increase in professional fees related to the recruitment of additional directors to our Board and various other consulting services, an increase related to proxy solicitation and distribution services, an increase in corporate insurance expenses and travel related expenses, as well as an increase in royalty expense related to the net sales of TLANDO resulting from its commercial launch in June 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 and candidates for which we are exploring partnering which target large addressable markets with significant unmet medical needs. Our candidates represent enablement of patient friendly oral delivery options for favorable benefit to risk profile.

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 LPCN 1144, our candidate for treatment of non-cirrhotic NASH, LPCN 1148, LPCN 1107, our candidate for prevention of pre-term birth, 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 Lip'ral 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.

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
	\$	\$
Cash and cash equivalents	2,396,960	2,950,552
Marketable investment securities	31,858,842	41,667,405
Accrued interest income	40,774	247,253
Contract asset - current portion	579,428	-
Prepaid and other current assets	1,234,536	1,514,465
Total current assets	<u>36,110,540</u>	<u>46,379,675</u>
Marketable investment securities	-	2,021,800
Contract asset - non-current portion	3,252,500	4,050,000
Property and equipment, net of accumulated depreciation of \$1,150,952 and \$1,144,077	37,435	7,211
Other assets	23,753	23,753
Total assets	<u>\$ 39,424,228</u>	<u>\$ 52,482,439</u>

Liabilities and Stockholders' Equity

Current liabilities:		
		\$
Accounts payable	\$ 630,456	1,289,342
Accrued expenses	880,850	1,016,458
Debt - current portion	-	2,310,825
Litigation settlement liability - current portion	-	1,000,000
Total current liabilities	<u>1,511,306</u>	<u>5,616,625</u>
Warrant liability	264,099	795,796
Litigation settlement liability - non-current portion	-	500,000
Total liabilities	<u>1,775,405</u>	<u>6,912,421</u>

Commitments and contingencies

Stockholders' equity:

Preferred stock, par value \$0.0001 per share, 10,000,000 shares authorized; zero issued and outstanding	-	-
Common stock, par value \$0.0001 per share, 200,000,000 shares authorized; 88,516,501 and 88,296,360 issued and 88,510,791 and 88,290,650 outstanding	8,851	8,829
Additional paid-in capital	218,952,749	218,286,324
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(76,935)	(18,016)
Accumulated deficit	(181,195,130)	(172,666,407)
Total stockholders' equity	<u>37,648,823</u>	<u>45,570,018</u>
Total liabilities and stockholders' equity	<u>\$ 39,424,228</u>	<u>\$ 52,482,439</u>

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

Three Months Ended September 30,		Nine Months Ended September 30,	
2022	2021	2022	2021

Revenues:	\$ -	\$ 54,994	\$ 500,000	\$ 54,994
Operating expenses:				
Research and development	2,100,432	2,366,521	6,886,398	5,411,748
General and administrative	798,939	1,222,146	3,172,144	4,281,690
Total operating expenses	<u>2,899,371</u>	<u>3,588,667</u>	<u>10,058,542</u>	<u>9,693,438</u>
Operating loss	<u>(2,899,371)</u>	<u>(3,533,673)</u>	<u>(9,558,542)</u>	<u>(9,638,444)</u>
Other income (expense):				
Interest and investment income	163,966	17,264	275,420	45,257
Interest expense	-	(44,839)	(27,098)	(171,241)
Unrealized gain on warrant liability	326,240	479,951	531,697	506,208
Gain (loss) litigation settlement liability	-	-	250,000	(4,000,000)
Total other income (expense), net	<u>490,206</u>	<u>452,376</u>	<u>1,030,019</u>	<u>(3,619,776)</u>
Loss before income tax expense	<u>(2,409,165)</u>	<u>(3,081,297)</u>	<u>(8,528,523)</u>	<u>(13,258,220)</u>
Income tax expense	-	-	(200)	(200)
Net loss	<u>\$(2,409,165)</u>	<u>\$(3,081,297)</u>	<u>\$(8,528,723)</u>	<u>\$(13,258,420)</u>
Basic loss per share attributable to common stock	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>	<u>\$ (0.10)</u>	<u>\$ (0.15)</u>
Weighted average common shares outstanding, basic	<u>88,506,479</u>	<u>88,290,650</u>	<u>88,439,198</u>	<u>86,477,640</u>
Diluted loss per share attributable to common stock	<u>\$ (0.03)</u>	<u>\$ (0.04)</u>	<u>\$ (0.10)</u>	<u>\$ (0.16)</u>
Weighted average common shares outstanding, diluted	<u>88,771,698</u>	<u>88,963,899</u>	<u>88,945,040</u>	<u>87,197,002</u>
Comprehensive loss:				
Net loss	\$(2,409,165)	\$(3,081,297)	\$(8,528,723)	\$(13,258,420)
Net unrealized gain (loss) on available-for-sale securities	7,972	(3,234)	(58,919)	(3,420)
Comprehensive loss	<u>\$(2,401,193)</u>	<u>\$(3,084,531)</u>	<u>\$(8,587,642)</u>	<u>\$(13,261,840)</u>

SOURCE Lipocine Inc.

For further information: For further information: Krista Fogarty, Phone: (801) 994-7383, kf@lipocine.com, Investors: Hans Vitzthum, Phone: (617) 430-7875, hans@lifesciadvisors.com

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