Lipocine Announces Financial Results for the First Quarter Ended March 31, 2022

SALT LAKE CITY, May 9, 2022 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on developing innovative products for neuroendocrine and metabolic disorders, today announced financial results for the quarter ended March 31, 2022 and provided a corporate update.

Program Highlights

- TLANDO™ was approved and granted Market Exclusivity by the U.S. Food and Drug Administration ("FDA") for hypogonadism and our licensee expects commercial launch in second quarter of 2022
- Lipocine is currently enrolling subjects in a Phase 2 proof-of-concept study to evaluate the therapeutic potential of LPCN 1148 for the management of cirrhosis, with enrollment in the study expected to be complete by the end of the third quarter of 2022
- Lipocine has requested an End of Phase 2 meeting to discuss the Phase 3 study and confirmatory trial design for LPCN 1144 in non-cirrhotic non-alcoholic steatohepatitis ("NASH")
- An open label extension ("OLE") study in non-cirrhotic NASH has been completed and topline results are expected in May 2022

Board Appointments

The company appointed Jill M. Jene, Ph.D. and Spyros Papapetropoulos, M.D., Ph.D. to its board of directors in April 2022

First Quarter Ended March 31, 2022 Financial Results

Lipocine reported a net loss of $3.5 million or ($0.04 per diluted share), for the quarter ended March 31, 2022, compared with a net loss of $3.4 million, or ($0.04) per diluted share, in the quarter ended March 31, 2021.

Research and development expenses were $1.9 million for the quarter ended March 31, 2022, compared with $1.6 million for the quarter ended March 31, 2021. The increase in research and development expenses for the quarter ended March 31, 2022, was a result of increases in contract research organization expenses related to the ongoing Phase 2 clinical study for LPCN 1148, PK and food effect studies for LPCN 1107 and LPCN 1154, manufacturing scale up expenses for LPCN 1111, and an increase in personnel and other R&D expenses. These increases were offset by a decrease in contract research organization expense and outside consulting costs related to the LPCN 1144 LiFT Phase 2 clinical study and a decrease in costs related to TLANDO.

General and administrative expenses were $1.2 million for the quarter ended March 31, 2022, compared with $1.5 million for the quarter ended March 31, 2021. The decrease in general and administrative expenses for the quarter ended March 31, 2022, was primarily due to decreases in legal costs, personnel costs and other general and administrative costs. These decreases were offset by increases in professional fees related to various consulting and proxy solicitation services as well as an increase in corporate insurance expenses.

As of March 31, 2022, the company had $42.0 million of unrestricted cash, cash equivalents and marketable investment securities compared to $46.6 million as of December 31, 2021.

About Lipocine

Lipocine Inc. is a biopharmaceutical company focused on neuroendocrine and metabolic disorders using its proprietary drug delivery technologies. Lipocine's clinical development pipeline includes: LPCN 1148, LPCN 1144, LPCN 1111, LPCN 1107 and oral neuroactive steroids including LPCN 1154 and LPCN 2101. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is approved by the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the management of symptoms associated with liver cirrhosis. LPCN 1144, an oral prodrug of bioidentical testosterone, recently completed a Phase 2 clinical study demonstrating potential utility in the treatment of non-cirrhotic NASH. LPCN 1111, a novel oral prodrug of testosterone, originated and is being developed by Lipocine as a next-generation oral testosterone product with potential for once-daily dosing. In a phase 2 clinical evaluation when administered as once or twice daily, LPCN 1111 met primary and secondary endpoints. LPCN 1107 is potentially the first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth and has been granted orphan drug designation by the FDA. Neuroactive steroids are currently being evaluated including LPCN 1154 for the potential treatment of postpartum depression and LPCN 2101 for the potential treatment of epilepsy. 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 Lipocine's 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, the potential uses and benefits of our product candidates, and our product development efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that 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.

*TLANDO® is a registered trademark assigned to Antares Pharma.

LIPOCINE INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 5,733,231	$ 2,950,552
Marketable investment securities	36,266,299	41,667,405
Accrued interest income	120,094	247,253
Prepaid and other current assets	1,377,925	1,514,465
Total current assets	43,497,549	46,379,675
Marketable investment securities	-	2,021,800
Contract asset	4,050,000	4,050,000
Property and equipment, net of accumulated depreciation of $1,145,796 and $1,144,077, respectively	32,289	7,211
Other assets	23,753	23,753
Total assets	$ 47,603,591	$ 52,482,439
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 469,887	$ 1,289,342
Accrued expenses	567,901	1,016,458
Debt - current portion	1,482,165	2,310,825
Litigation settlement liability - current portion	1,000,000	1,000,000
Total current liabilities	3,519,953	5,616,625
Warrant liability	1,173,785	795,796
Litigation settlement liability - non-current portion	500,000	500,000
Total liabilities	5,193,738	6,912,421
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, 100,000,000		

shares authorized; 88,504,634 and 88,296,360 issued and 88,498,924 and 88,290,650 outstanding	8,850	8,829
Additional paid-in capital	218,663,319	218,286,324
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(67,416)	(18,016)
Accumulated deficit	(176,154,188)	(172,666,407)
Total stockholders' equity	42,409,853	45,570,018
Total liabilities and stockholders' equity	$ 47,603,591	$ 52,482,439

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Revenues	$ -	$ -
Operating expenses:		
Research and development	1,887,953	1,580,540
General and administrative	1,243,687	1,533,953
Total operating expenses	3,131,640	3,114,493
Operating loss	(3,131,640)	(3,114,493)
Other income (expense):		
Interest and investment income	41,576	10,649
Interest expense	(19,529)	(68,973)
Unrealized loss on warrant liability	(377,988)	(195,065)
Total other expense, net	(355,941)	(253,389)
Loss before income tax expense	(3,487,581)	(3,367,882)
Income tax expense	(200)	(200)
Net loss	$ (3,487,781)	$ (3,368,082)
Basic loss per share attributable to common stock	$ (0.04)	$ (0.04)
Weighted average common shares outstanding, basic	88,309,628	81,881,392
Diluted loss per share attributable to common stock	$ (0.04)	$ (0.04)
Weighted average common shares outstanding, diluted	88,309,628	81,881,392
Comprehensive loss:		
Net loss	$ (3,487,781)	$ (3,368,082)
Net unrealized loss on available-for-sale securities	(49,400)	(22,459)
Comprehensive loss	$ (3,537,181)	$ (3,390,541)

SOURCE Lipocine Inc.

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