

Lipocine Announces Financial Results for the First Quarter Ended March 31, 2021

SALT LAKE CITY, May 6, 2021 /[PRNewswire](#)/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced financial results for the first quarter ended March 31, 2021 and provided a corporate update.

First Quarter Recent Corporate Highlights

- Announced positive topline results from the Phase 2 *LiFT* ("Liver Fat intervention with oral Testosterone") clinical study, investigating LPCN 1144 in biopsy-confirmed NASH male subjects
 - Both LPCN 1144 treatment arms met the primary endpoint, change in hepatic fat fraction via magnetic resonance imaging proton density fat fraction ("MRI-PDFF"), with statistical significance
 - 36-week biopsy data from the *LiFT* study are expected in August 2021
- Continued enrolling patients into an open label extension to the *LiFT* clinical study in which all patients will have access to LPCN 1144
- Announced the publication of results supporting the therapeutic potential of LPCN 1144 in the treatment of non-alcoholic steatohepatitis ("NASH") and hepatic fibrosis
 - The results were featured in a paper entitled "[Treatment Potential of LPCN 1144 on Liver Health and Metabolic Regulation in a Non-Genomic, High Fat Diet Induced NASH Rabbit Model](#)" (Comeglio et al), published in the Journal of Endocrinological Investigation
- Continued to evaluate commercial options for TLANDO, our oral testosterone product for testosterone replacement therapy ("TRT") in adult males with hypogonadism
- Posters featuring clinical data on TLANDO™ were presented at the ENDO 2021 Conference
- Raised gross proceeds of approximately \$28.7 million in a public offering of approximately 16.4 million shares of common stock

First Quarter Ended March 31, 2021 Financial Results

Lipocine reported a net loss of \$3.4million, or (\$0.04) per diluted share, for the first quarter ended March 31, 2021, compared with a net loss of \$5.8 million, or (\$0.14) per diluted share, for the first quarter ended March 31, 2020.

Research and development expenses were \$1.6 million for the first quarter ended March 31, 2021, compared with \$2.5 million for the first quarter ended March 31, 2020. The decrease in research and development expenses during the three months ended March 31, 2021 was primarily due to a decrease in contract research organization expense and outside consulting costs related to the LPCN 1144 *LiFT* Phase 2 clinical study in NASH subjects and a decrease in raw material costs of TLANDO XR offset by increases in personnel expense and other R&D expenses.

General and administrative expenses were \$1.5 million for the first quarter ended March 31, 2021, compared with \$2.1 million for the first quarter ended March 31, 2020. The decrease in general and administrative expenses during the three months ended March 31, 2021 was primarily due to a decrease in legal costs due to less activity in 2021 as compared to 2020 in the following activities: lawsuit filed against Clarus Therapeutics Inc. for patent infringement in April 2019 and the on-going class action lawsuit defense. Additionally, personnel costs decreased in 2021. These decreases were offset by an increase in corporate insurance expenses.

As of March 31, 2021, the Company had \$50.0 million of unrestricted cash, cash equivalents, and marketable investments, compared to \$19.7 million of unrestricted cash, cash equivalents and marketable investment securities as of December 31, 2020.

About Lipocine

Lipocine Inc. is a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders using its proprietary drug delivery technologies. Lipocine's clinical development pipeline includes: TLANDO, LPCN 1144, TLANDO XR, LPCN 1148 and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, has received tentative approval from the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. LPCN 1144, an oral prodrug of bioidentical testosterone, recently completed a proof-of-concept clinical study demonstrating the potential utility in the treatment of non-cirrhotic NASH. LPCN 1144 is currently being studied in a Phase 2 clinical study. TLANDO XR, 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 daily or twice daily TLANDO XR met the typical primary and secondary end points. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the management of cirrhosis. 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. 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 timing of completion of clinical trials, 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.

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,601,594	\$ 19,217,382
Restricted cash	-	5,000,000
Marketable investment securities	29,747,465	449,992
Accrued interest income	136,387	391
Prepaid and other current assets	458,423	661,258
Total current assets	45,943,869	25,329,023
Marketable investment securities	4,608,999	-
Other assets	23,753	23,753
Total assets	<u>\$ 50,576,621</u>	<u>\$ 25,352,776</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 558,344	\$ 1,597,220
Accrued expenses	1,504,907	1,653,178
Debt - current portion	3,333,333	3,333,333
Total current liabilities	5,396,584	6,583,731
Debt - non-current portion	1,442,437	2,257,075
Warrant liability	1,346,751	1,170,051
Total liabilities	<u>8,185,772</u>	<u>10,010,857</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, 100,000,000 shares authorized; 88,296,360 and 70,041,967 issued and 88,290,650 and 70,036,257 outstanding	8,830	7,005
Additional paid-in capital	217,845,280	187,407,634
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(22,459)	-
Accumulated deficit	(175,400,090)	(172,032,008)
Total stockholders' equity	<u>42,390,849</u>	<u>15,341,919</u>
Total liabilities and stockholders' equity	<u>\$ 50,576,621</u>	<u>\$ 25,352,776</u>

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

Three Months Ended March 31, 2021 2020

Operating expenses:		
Research and development	1,580,540	2,511,754
General and administrative	1,533,953	2,085,261
Total operating expenses	<u>3,114,493</u>	<u>4,597,015</u>
Operating loss	<u>(3,114,493)</u>	<u>(4,597,015)</u>
Other income (expense):		
Interest and investment income	10,649	59,938
Interest expense	(68,973)	(133,345)
Unrealized loss on warrant liability	(195,065)	(1,100,029)
Total other expense, net	<u>(253,389)</u>	<u>(1,173,436)</u>
Loss before income tax expense	<u>(3,367,882)</u>	<u>(5,770,451)</u>
Income tax expense	(200)	(200)
Net loss	<u>\$ (3,368,082)</u>	<u>\$ (5,770,651)</u>
Basic loss per share attributable to common stock	<u>\$ (0.04)</u>	<u>\$ (0.14)</u>
Weighted average common shares outstanding, basic	<u>81,881,392</u>	<u>41,347,631</u>
Diluted loss per share attributable to common stock	<u>\$ (0.04)</u>	<u>\$ (0.14)</u>
Weighted average common shares outstanding, diluted	<u>81,881,392</u>	<u>41,347,631</u>
Comprehensive loss:		
Net loss	\$ (3,368,082)	\$ (5,770,651)
Net unrealized gain (loss) on available-for-sale securities	(22,459)	38
Comprehensive loss	<u>\$ (3,390,541)</u>	<u>\$ (5,770,613)</u>

SOURCE Lipocine Inc.

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<https://ir.lipocine.com/2021-05-06-Lipocine-Announces-Financial-Results-for-the-First-Quarter-Ended-March-31,-2021>