Lipocine Announces First Quarter 2020 Financial and Operational Results

SALT LAKE CITY, May 7, 2020 /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, 2020, and provided a corporate update.

First Quarter and Recent Corporate Highlights

- Resubmitted New Drug Application ("NDA") for TLANDO™, the Company's oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males with hypogonadism
    - The U.S. Food and Drug Administration ("FDA") acknowledged receipt of resubmission and established August 28, 2020 as the target Prescription Drug User Fee Act ("PDUFA") goal date
- Received FDA clearance on Investigational New Drug ("IND") application for Phase 2 clinical study with LPCN 1148 for the treatment of non-alcoholic steatohepatitis ("NASH") in cirrhotic patients
- Raised $6.0 million in gross proceeds in a registered direct offering of common stock and warrants in February 2020
- Received decision from the U.S. Court of Appeals for the Federal Circuit affirming the decision of the United States Patent and Trademark Office ("USPTO") in the patent interference case between Lipocine and Clarus Therapeutics

First Quarter Ended March 31, 2020 Financial Results
Lipocine reported a net loss of $5.8 million, or ($0.14) per diluted share, for the quarter ended March 31, 2020, compared with a net loss of $3.2 million, or ($0.14) per diluted share, for the quarter ended March 31, 2019.

Research and development expenses were $2.5 million for the quarter ended March 31, 2020, compared with $1.9 million for the quarter ended March 31, 2019. The increase in research and development expenses during the three months ended March 31, 2020 was primarily due to increased contract research organization and outside consulting and manufacturing costs for the LPCN 1144 *LiFT* Phase 2 clinical study in NASH subjects of $1.7 million, a $50,000 increase in costs for TLANDO XR and a $56,000 increase in personnel expense. These increases were offset by a $1.2 million decrease in costs incurred relating to TLANDO, including the completion of the ABPM study and the filing of the NDA in the first half of 2019 and a $12,000 decrease in contract manufacturing costs for LPCN 1107.

General and administrative expenses were $2.1 million for the quarter ended March 31, 2020, compared with $1.2 million for the quarter ended March 31, 2019. The increase in general and administrative expenses during the three months ended March 31, 2020 was primarily due to a $1.0 million increase in legal costs associated with the lawsuit filed against Clarus for patent infringement in April 2019 in addition to costs associated with interference cases filed against Clarus, offset by a $59,000 decrease in personnel costs and a $26,000 decrease in administrative travel expenses.

As of March 31, 2020, Lipocine had $15.6 million of unrestricted cash, cash equivalents and marketable investment securities compared to $14.1 million at December 31, 2019. Additionally, the Company had $5.0 million of restricted cash, which is required to be maintained as cash collateral under the SVB Loan and Security Agreement until TLANDO is approved by the FDA. The Company believes that its existing capital resources will be sufficient to meet its projected operating requirements through at least February 15, 2021.

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, is designed to help restore normal testosterone levels in hypogonadal men. Lipocine has resubmitted its NDA to the FDA for TLANDO and has a PDUFA date of August 28, 2020. LPCN 1144, an oral product of bioidentical testosterone, recently completed a proof-of-concept clinical study demonstrating the potential utility in the treatment of pre-cirrhotic NASH. 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 treatment of NASH cirrhosis. LPCN 1107 is potentially the first oral hydroxyprogesterone caproate product candidate, with end of phase 2 meeting completed, 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. 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, risk related to on-going litigation 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, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 15,134,789	$ 9,728,523
Restricted cash	5,000,000	5,000,000
Marketable investment securities	448,077	4,340,041
Accrued interest income	9,212	16,522
Prepaid and other current assets	373,370	545,887
Total current assets	20,965,448	19,630,973
Property and equipment, net of accumulated depreciation of $1,140,942 and $1,140,143, respectively	2,755	3,554
Other assets	23,753	23,753
Total assets	$ 20,991,956	$ 19,658,280
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,654,909	$ 1,182,241
Accrued expenses	738,280	449,303
Debt - current portion	1,666,666	3,333,333
Total current liabilities	4,059,855	4,964,877
Debt - non-current portion	4,688,136	3,814,407
Warrant liability	5,691,229	4,591,200
Total liabilities	14,439,220	13,370,484
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; 47,860,209 and 37,655,175 issued and 47,854,499 and 37,649,465 outstanding	4,786	3,766
Additional paid-in capital	163,426,502	157,391,969

Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	-	(38)
Accumulated deficit	(156,837,840)	(151,067,189)
Total stockholders' equity	6,552,736	6,287,796
Total liabilities and stockholders' equity	$ 20,991,956	$ 19,658,280

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

	Three Months Ended March 31,	
	2020	**2019**
Operating expenses:		
Research and development	2,511,754	1,949,821
General and administrative	2,085,261	1,175,927
Total operating expenses	4,597,015	3,125,748
Operating loss	(4,597,015)	(3,125,748)
Other income (expense):		
Interest and investment income	59,938	125,265
Interest expense	(133,345)	(223,789)
Total other expense, net	(73,407)	(98,524)
Unrealized loss on warrant liability	(1,100,029)	-
Loss before income tax expense	(5,770,451)	(3,224,272)
Income tax expense	(200)	(200)
Net loss	$ (5,770,651)	$ (3,224,472)
Basic loss per share attributable to common stock	$ (0.14)	$ (0.14)
Weighted average common shares outstanding, basic	41,347,631	23,383,008
Diluted loss per share attributable to common stock	$ (0.14)	$ (0.14)
Weighted average common shares outstanding, diluted	41,347,631	23,383,008
Comprehensive loss:		
Net loss	$ (5,770,651)	$ (3,224,472)
Net unrealized gain on available-for-sale securities	38	2,352
Comprehensive loss	$ (5,770,613)	$ (3,222,120)

SOURCE Lipocine Inc.

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