Lipocine Announces Second Quarter 2020 Financial and Operational Results

SALT LAKE CITY, Aug. 6, 2020 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced financial results for the second quarter ended June 30, 2020 and provided a corporate update.

Second Quarter and Recent Corporate Highlights

- Presented clinical data on TLANDO™ at the American Urological Association ("AUA") Virtual Experience
  - Impact of a New Oral Testosterone Undecanoate on Blood Pressure and Cardiovascular Risk
  - A Novel Oral Testosterone Therapy Restores Testosterone to Eugonadal Levels Without Dose Titration
  - Effects of a New Oral Testosterone Undecanoate ("TLANDO") on Liver
- Announced that the treatment potential of LPCN 1144 was demonstrated in a pre-clinical non-alcoholic steatohepatitis ("NASH") and hepatic fibrosis model
- Received FDA clearance on an Investigational New Drug ("IND") application for a Phase 2 clinical study with LPCN 1148 for the treatment of cirrhosis
- Received a 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 Inc. ("Clarus")
- Received decision from Chancery Court of Delaware dismissing the shareholder derivative action filed against Lipocine's board of directors

Ongoing Activities and Upcoming Milestones

- TLANDO New Drug Application ("NDA") for use in adult males for conditions associated with hypogonadism under review by the U.S. Food and Drug Administration ("FDA") with a Prescription Drug User Fee Act ("PDUFA") target action date of August 28, 2020
- LPCN 1144 Phase 2 *LiFT* ("Liver Fat intervention with oral Testosterone") Phase 2 clinical study, a paired-biopsy study in confirmed pre-cirrhotic NASH subjects, has been initiated with enrollment continuing and top-line primary endpoint results expected by the end of 2020
- Intellectual property infringement lawsuit against Clarus is on-going, including fact discovery and expert testimony, with the jury trial scheduled for February 2021

Second Quarter Ended June 30, 2020 Financial Results
Lipocine reported a net loss of $6.4 million, or ($0.13) per diluted share, for the quarter ended June 30, 2020, compared with a net loss of $3.4 million, or ($0.14) per diluted share, in the quarter ended June 30, 2019.

Research and development expenses were $2.3 million for the quarter ended June 30, 2020, compared with $2.0 million for the quarter ended June 30, 2019. The increase in research and development expenses during the three months ended June 30, 2020 was primarily due to increased contract research organization and outside consulting and manufacturing costs related to the LPCN 1144 *LiFT* Phase 2 clinical study in NASH subjects of $965,000, as well as a $213,000 increase in personnel expense. These increases were offset by a $727,000 decrease in costs incurred in conjunction with TLANDO with the completion of the ABPM study in the first half of 2019, a $96,000 decrease in costs for TLANDO XR, a $25,000 decrease in contract manufacturing costs for LPCN 1107 and a $25,000 decrease in other research and development expenses.

General and administrative expenses were $2.0 million for the quarter ended June 30, 2020, compared with $1.4 million for the quarter ended June 30, 2019. The increase in general and administrative expenses during the three months ended June 30, 2020 was primarily due to a $613,000 increase in legal costs associated with the following activities: lawsuit filed against Clarus Therapeutics Inc. for patent infringement in April 2019, interference cases filed against Clarus and the on-going class action lawsuit defense. In addition, there was a $48,000 increase in personnel costs, offset by a $41,000 decrease marketing expense, a $34,000 decrease in administrative travel expenses and a $19,000 decrease in other general and administrative expenses.

As of June 30, 2020, we had $18.3 million of unrestricted cash, cash equivalents and marketable investment securities compared to $14.1 million at December 31, 2019. Additionally, as of June 30, 2020 and December 31, 2019 we 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.

Six Months Ended June 30, 2020 Financial Results
Lipocine reported a net loss of $12.1 million, or ($0.27) per diluted share, for the six months ended June 30, 2020, compared with a net loss of $6.7 million, or ($0.28) per diluted share, for the six months ended June 30, 2019.

Research and development expenses were $4.8 million for the six months ended June 30, 2020, compared with $3.9 million for the six months ended June 30, 2019. The increase in research and development expenses during the six months ended June 30, 2020 was primarily due to increased contract research organization and outside consulting and manufacturing costs related to the LPCN 1144 *LiFT* Phase 2 clinical study in NASH subjects of $2.6 million and a $270,000 increase in personnel expense. These increases were offset by a $1.9 million decrease in costs incurred in conjunction with TLANDO with the completion of the ABPM study in the first half of 2019, a $46,000 decrease in costs for TLANDO XR, a $37,000 decrease in contract manufacturing costs for LPCN 1107 and a $20,000 decrease in other research and development expenses.

General and administrative expenses were $4.0 million for the six months ended June 30, 2020, compared with $2.6 million for the six months ended June 30, 2019. The increase in general and administrative expenses during the six months ended June 30, 2020 was primarily due to a $1.6 million increase in legal costs associated with the following activities: lawsuit filed against Clarus Therapeutics Inc. for patent infringement in April 2019, interference cases filed against Clarus and the on-going class action lawsuit defense, offset by a $11,000 decrease in personnel costs, a $60,000 decrease in administrative travel expense, a $41,000 decrease in marketing expense and a $112,000 decrease in other general and administrative expenses.

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 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 treatment of 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 and related clinical trials, the timing of completion of clinical trials, the potential uses and benefits of our product candidates, our product development efforts, and potential future actions by the FDA related to TLANDO, including the PDUFA date. 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)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
	$	$
Cash and cash equivalents	13,837,818	9,728,523
Restricted cash	5,000,000	5,000,000
Marketable investment securities	4,466,541	4,340,041
Accrued interest income	7,919	16,522
Prepaid and other current assets	147,308	545,887
Total current assets	23,459,586	19,630,973
Property and equipment, net of accumulated depreciation of $1,141,741 and $1,140,143, respectively	1,956	3,554
Other assets	23,753	23,753
	$	$
Total assets	23,485,295	19,658,280
Liabilities and Stockholders' Equity		
Current liabilities:		
	$	$
Accounts payable	906,826	1,182,241
Accrued expenses	993,258	449,303
Debt - current portion	2,331,710	3,333,333
Total current liabilities	4,231,794	4,964,877
Debt - non-current portion	4,002,221	3,814,407
Warrant liability	2,166,312	4,591,200
Total liabilities	10,400,327	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; 61,383,016 and 37,655,175 issued and 61,377,306 and 37,649,465 outstanding	6,138	3,766
Additional paid-in capital	176,327,120	157,391,969
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(104)	(38)

Accumulated deficit	(163,207,474)	(151,067,189)
Total stockholders' equity	13,084,968	6,287,796
Total liabilities and stockholders' equity	$ 23,485,295	$ 19,658,280

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 2,268,984	$ 1,964,146	$ 4,780,739	$ 3,913,966
General and administrative	1,953,535	1,386,457	4,038,795	2,562,385
Total operating expenses	4,222,519	3,350,603	8,819,534	6,476,351
Operating loss	(4,222,519)	(3,350,603)	(8,819,534)	(6,476,351)
Other income (expense):				
Interest and investment income	7,177	124,581	67,115	249,846
Interest expense	(87,847)	(204,575)	(221,192)	(428,364)
Loss on warrant liability	(2,066,445)	-	(3,166,474)	-
Total other expense, net	(2,147,115)	(79,994)	(3,320,551)	(178,518)
Loss before income tax expense	(6,369,634)	(3,430,597)	(12,140,085)	(6,654,869)
Income tax expense	-	-	(200)	(200)
Net loss	$ (6,369,634)	$ (3,430,597)	$ (12,140,285)	$ (6,655,069)
Basic loss per share attributable to common stock	$ (0.13)	$ (0.14)	$ (0.27)	$ (0.28)
Weighted average common shares outstanding, basic	49,769,253	24,591,419	45,558,442	23,990,552
Diluted loss per share attributable to common stock	$ (0.13)	$ (0.14)	$ (0.27)	$ (0.28)
Weighted average common shares outstanding, diluted	49,769,253	24,591,419	45,558,442	23,990,552
Comprehensive loss:				
Net loss	$ (6,369,634)	$ (3,430,597)	$ (12,140,285)	$ (6,655,069)
Net unrealized gain (loss) on available-for-sale securities	(104)	1,528	(66)	3,880
Comprehensive loss	$ (6,369,738)	$ (3,429,069)	$ (12,140,351)	$ (6,651,189)

SOURCE Lipocine Inc.

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