Lipocine Announces 2019 Year End Financial and Operational Results

SALT LAKE CITY, March 13, 2020 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company, today announced financial results for the year ended December 31, 2019, and provided a corporate update.

Fourth Quarter and Recent Corporate Highlights

- Resubmitted the New Drug Application ("NDA") in February 2020 for TLANDO™, the Company's oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism.
    - The NDA resubmission was made following a Post Action Meeting with the U.S. Food and Drug Administration ("FDA") to discuss a potential path forward for TLANDO. The NDA incorporates the reanalysis of existing data based on written feedback from the FDA to address the deficiency from the Complete Response Letter ("CRL") received from the FDA in November 2019.
    - The FDA has assigned a Prescription Drug User Fee Act ("PDUFA") goal date of August 28, 2020.
- Continued to actively enroll in the ongoing LPCN 1144 *LiFT* ("Liver Fat intervention with oral Testosterone") Phase 2 clinical study, a paired-biopsy study in confirmed pre-cirrhotic non-alcoholic steatohepatitis ("NASH") patients.
    - Top-line liver fat reduction data, as measured by MRI-PDFF at 12 weeks, are expected in the second half of 2020, followed by 36-week biopsy data which are expected by the first half of 2021.
- Raised $6.0 million in gross proceeds in a registered direct offering of common stock and warrants in February 2020.
- Raised $6.0 million in gross process in a public offering of common stock and warrants in November 2019.

"We are pleased that the FDA has assigned a new PDUFA date for TLANDO and are committed to working with the Agency towards the goal of achieving approval of TLANDO," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. "Based on the recent Post Action Meeting and subsequent written feedback, the FDA has indicated our approach to addressing the deficiency from the most recent CRL appears to be a reasonable path forward. In parallel, we continue to develop LPCN 1144 for the treatment of NASH and look forward to announcing top line liver fat data from the ongoing *LiFT* clinical study in the second half of 2020."

Year Ended December 31, 2019 Financial Results
Lipocine reported a net loss of $13.0 million, or ($0.50) per diluted share, for the year ended December 31, 2019, compared with a net loss of $11.7 million, or ($0.55) per diluted share, for the year ended December 31, 2018.

Research and development expenses were $7.5 million for the year ended December 31, 2019, compared with $6.5 million for the year ended December 31, 2018. The increase in research and development expenses during the year ended December 31, 2019 was primarily due to increases in contract research organization and outside consulting and manufacturing costs for LPCN 1144 and an increase in costs for TLANDO XR (LPCN 1111), offset by a decrease in costs incurred in conjunction with TLANDO with the completion of the ABPM study and the filing of the NDA in the first half of 2019, a decrease in contract manufacturing costs for LPCN 1107 and a decrease in personnel expense.

General and administrative expenses were $5.6 million for the year ended December 31, 2019, compared with $5.3 million for the year ended December 31, 2018. The increase in general and administrative expenses was primarily due to increases in legal and corporate insurance costs offset by a decrease in personnel costs.

As of December 31, 2019, the Company had $14.1 million of unrestricted cash, cash equivalents and marketable investment securities compared to $15.3 million at December 31, 2018. Additionally, as of December 31, 2019 and December 31, 2018 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. In February 2020, the Company raised an additional $6.0 million in gross proceeds from a registered direct offering of common stock and warrants.

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 1111"), 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 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, enrollment of patients in the *LiFT* study, the completion of and timing of data from the *LiFT* study, the potential uses and benefits of our product candidates, our product development efforts, and future discussions 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, risk related to on-going litigation, competition including from companies with approved competitive drugs, 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
Consolidated Balance Sheets
December 31, 2019 and 2018

	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	$ 9,728,523	$ 8,077,539
Restricted cash	5,000,000	5,000,000
Marketable investment securities	4,340,041	7,173,037
Accrued interest income	16,522	38,514
Prepaid and other current assets	545,887	520,113
Total current assets	19,630,973	20,809,203
Property and equipment, net of accumulated depreciation of $1,140,143 and $1,124,700, respectively	3,554	18,997
Other assets	23,753	23,753
Total assets	$ 19,658,280	$ 20,851,953
Liabilites and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,182,241	$ 671,280
Accrued expenses	449,303	487,135
Debt - current portion	3,333,333	3,333,333
Total current liabilities	4,964,877	4,491,748

Debt - non-current portion	3,814,407	6,926,532
Warrant liability	4,591,200	-
Total liabilities	13,370,484	11,418,280
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; 37,655,175 and 21,737,196 issued and 37,649,465 and 21,731,486 outstanding	3,766	2,174
Additional paid-in capital	157,391,969	147,533,019
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(38)	(963)
Accumulated deficit	(151,067,189)	(138,059,845)
Total stockholders' equity	6,287,796	9,433,673
Total liabilities and stockholders' equity	$ 19,658,280	$ 20,851,953

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

Years Ended December 31, 2019 and 2018

	2019	**2018**
Revenues:		
License revenue	$ 164,990	$ 428,031
Total revenues	164,990	428,031
Operating expenses:		
Research and development	7,468,210	6,464,708
General and administrative	5,597,070	5,289,142
Total operating expenses	13,065,280	11,753,850
Operating loss	(12,900,290)	(11,325,819)
Other expense, net	(343,254)	(333,503)
Unrealized gain on warrant liability	236,400	-
Loss before income tax expense	(13,007,144)	(11,659,322)
Income tax expense	(200)	(700)
Net loss	$ (13,007,344)	$ (11,660,022)
Basic loss per share attributable to common stock	$ (0.50)	$ (0.55)
Weighted average common shares outstanding, basic	25,882,273	21,352,339
Diluted loss per share attributable to common stock	$ (0.50)	$ (0.55)
Weighted average common shares outstanding, diluted	25,882,273	21,352,339
Comprehensive loss:		
Net loss	$ (13,007,344)	$ (11,660,022)
Unrealized net gain on available-for-sale securities	925	3,653

Comprehensive loss	$ (13,006,419)	$ (11,656,369)

SOURCE Lipocine Inc.

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