Lipocine Announces Third Quarter 2019 Financial and Operational Results

SALT LAKE CITY, Nov. 12, 2019 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company, today announced financial results for the third quarter and nine months ended September 30, 2019, and provided a corporate update.

Third Quarter and Recent Corporate Highlights

- TLANDO™, our oral testosterone replacement therapy ("TRT") product, received a Complete Response Letter ("CRL") from the United Stated Food and Drug Administration ("FDA") on November 8, 2019
- First patient has been dosed in *LiFT* ("Liver Fat intervention with oral Testosterone") Phase 2 clinical study of LPCN 1144 in confirmed pre-cirrhotic non-alcoholic steatohepatitis ("NASH") subjects.
    - The LiFT Phase 2 clinical study is a prospective, multi-center, randomized, double-blind, placebo-controlled multiple-arm study in biopsy-confirmed male NASH subjects with grade F2/F3 fibrosis and a NAFLD Activity Score ("NAS") ≥ 4 with a 36-week treatment period.
    - Top-line primary end point liver fat reduction data are currently expected in mid-2020, as measured by MRI-PDFF at 12 weeks, followed by 36-week biopsy data.
- Data from a clinical trial of LPCN 1144 in non-alcoholic fatty liver disease ("NAFLD") were selected for presentation at The Liver Meeting® 2019, held November 8th – 12th in Boston, MA.
    - Lipocine's abstract was selected by the Scientific Program Committee of the American Association for the Study of Liver Disease ("AASLD") as a Poster of Distinction for presentation.
- Four abstracts (two oral presentations and two poster presentation on TLANDO) were presented at the 20th Annual Fall Meeting of the Sexual Medicine Society of North America ("SMSNA"), October 24-27th in Nashville, TN.
- The U.S. District Court of Delaware has set a trial date for Lipocine's patent infringement lawsuit against Clarus's JATENZO® drug product relating to six of Lipocine's U.S. patents.
    - Trial is set to begin August 24, 2020 at which time Lipocine plans to seek a permanent injunction for Clarus's infringement.

"During the third quarter, we continued to advance our pipeline, with important milestones achieved," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. "We are excited to continue enrolling subjects in the ongoing LPCN 1144 *LiFT* clinical study and look forward to participating in the TLANDO Post Action meeting with FDA to discuss a potential path forward for the approval of TLANDO while reserving our right to request for formal dispute resolution," said Dr. Mahesh Patel.

Third Quarter Ended September 30, 2019 Financial Results

Lipocine reported a net loss of $3.1 million, or ($0.12) per diluted share, for the quarter ended September 30, 2019, compared with a net loss of $2.5 million, or ($0.12) per diluted share, in the quarter ended September 30, 2018.

License revenue was $165,000 during the three months ended September 30, 2019 compared to no license revenue being recognized during the three months ended September 30, 2018. License revenue in 2019 relates to royalty payments received from Spriaso, LLC ("Spriaso") under a licensing agreement in the cough and cold field.

Research and development expenses were $1.7 million for the quarter ended September 30, 2019, compared with $1.4 million for the quarter ended September 30, 2018. The increase in research and development expenses was primarily due to increases in outside service costs related to the ramping up of the LPCN 1144 *LiFT* Phase 2 clinical study and increases in other research and development costs, offset by decreased contract research organization and outside consulting costs for TLANDO in connection with the completion of the ABPM study and filing of the NDA and a decrease in personnel costs. The decrease in personnel costs primarily relate to decreased stock compensation expense which resulted from the reversal of stock-based compensation expense recorded for the expected vesting of restricted stock units upon the approval of TLANDO (previously estimated to vest in the fourth quarter of 2019). The decrease in stock-based compensation expense was offset by increased salaries and other personnel expenses.

General and administrative expenses were $1.4 million for the quarter ended September 30, 2019, compared with $0.9 million for the quarter ended September 30, 2018. The increase in general and administrative was primarily due to an increase in legal fees mainly due to the lawsuit filed against Clarus for patent infringement and increases in other general and administrative expenses, offset by a decrease in personnel costs attributable to the reversal of stock-based compensation expense recorded for the expected vesting of restricted stock units upon the approval of TLANDO (previously estimated to vest in the fourth quarter of 2019).

As of September 30, 2019, the Company had unrestricted cash, cash equivalents and marketable securities aggregating $11.5 million, compared to $15.3 million at December 31, 2018. Additionally, as of September 30, 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 Loan and Security Agreement with Silicon Valley Bank until TLANDO is approved by the FDA.

Nine Months Ended September 30, 2019 Financial Results

Lipocine reported a net loss of $9.7 million, or ($0.40) per diluted share, for the nine months ended September 30, 2019, compared with a net loss of $8.4 million, or ($0.40) per diluted share, in the nine months ended September 30, 2018.

License revenue was $165,000 during the nine months ended September 30, 2019 compared to license revenue of $428,000 during the three months ended September 30, 2018. License revenue in both 2019 and 2018 relates to royalty payments received from Spriaso under a licensing agreement in the cough and cold field.

Research and development expenses were $5.6 million for the nine months ended September 30, 2019, compared with $4.3 million for the nine months ended September 30, 2018. The increase in research and development expenses was primarily due to increases in the following costs: contract research organization and outside consulting costs for TLANDO in connection with completion of the ABPM study and the filing of the NDA, increased manufacturing costs for TLANDO, increased outside service costs related to the second quarter initiation of the LPCN 1144 *LiFT* Phase 2 clinical study, increased outside contract research organization costs related to TLANDO XR (LPCN 1111), increases in miscellaneous other research and development expenses and increased personnel costs. These cost increases were offset by a decrease in personnel costs attributable primarily to the reversal of stock-based compensation expense recorded for the expected vesting of restricted stock units upon the approval of TLANDO (previously estimated to vest in the fourth quarter of 2019) and decreased contract manufacturing costs for LPCN 1107.

General and administrative expenses were $4.0 million for the quarter ended September 30, 2019, compared with $4.3 million for the quarter ended September 30, 2018. The decrease in general and administrative was primarily due to decreased personnel costs, including decreased salaries and benefits due to the elimination of our commercial sales and marketing team in 2018, a decrease in severance compensation, and a net decrease in stock-based compensation mainly due to reversal of stock-based compensation expense recorded for the expected vesting of restricted stock units upon the approval of TLANDO (previously estimated to vest in the fourth quarter of 2019) and increases in other general and administrative expenses. These decreases in personnel costs and other general and administrative expenses were offset by increases in legal fees mainly due to the lawsuit filed against Clarus for patent infringement and increases in corporate insurance.

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 development programs. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men and received a Complete Response Letter from the U.S. Food and Drug Administration on November 8, 2019. LPCN 1144, a differentiated oral product of bioidentical testosterone, is currently undergoing Phase 2 clinical testing in biopsy confirmed NASH patients and recently completed a proof-of-concept clinical study demonstrating the potential utility the in treatment of NASH. TLANDO XR (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 and has completed Phase 2 testing. LPCN 1148 is a unique oral testosterone product targeted to treat NASH 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. An End of Phase 2 meeting with the FDA has been completed. 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 expectation that it will continue the *LiFT* Phase 2 clinical study, future discussions and actions with the FDA related to TLANDO, 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)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 6,664,508	$ 8,077,539
Restricted cash	5,000,000	5,000,000
Marketable investment securities	4,880,876	7,173,037
Accrued interest income	10,854	38,514
Prepaid and other current assets	754,504	520,113
Total current assets	17,310,742	20,809,203
Property and equipment, net of accumulated depreciation of $1,136,283 and $1,124,700, respectively	7,415	18,997
Other assets	23,753	23,753
Total assets	$ 17,341,910	$ 20,851,953
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,360,446	$ 671,280
Accrued expenses	540,954	487,135
Debt - current portion	3,333,333	3,333,333
Total current liabilities	5,234,733	4,491,748
Debt - non-current portion	4,601,837	6,926,532
Total liabilities	9,836,570	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; 25,033,482 and 21,737,196 issued and 25,027,772 and 21,731,486 outstanding	2,503	2,174
Additional paid-in capital	155,318,402	147,533,019
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive income (loss)	261	(963)
Accumulated deficit	(147,775,114)	(138,059,845)
Total stockholders' equity	7,505,340	9,433,673

Total liabilities and stockholders' equity	$ 17,341,910	$ 20,851,953

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
License revenue	$ 164,990	$ -	$ 164,990	$ 428,031
Total revenues	164,990	-	164,990	428,031
Operating expenses:				
Research and development	1,713,417	1,422,919	5,626,883	4,282,823
General and administrative	1,427,261	930,137	3,989,645	4,299,659
Total operating expenses	3,140,678	2,353,056	9,616,528	8,582,482
Operating loss	(2,975,688)	(2,353,056)	(9,451,538)	(8,154,451)
Other income (expense):				
Interest and investment income	98,988	112,561	348,833	343,145
Interest expense	(183,500)	(218,577)	(611,864)	(622,537)
Total other expense, net	(84,512)	(106,016)	(263,031)	(279,392)
Loss before income tax expense	(3,060,200)	(2,459,072)	(9,714,569)	(8,433,843)
Income tax expense	-	-	(700)	(700)
Net loss	$(3,060,200)	$(2,459,072)	$ (9,715,269)	$(8,434,543)
Basic loss per share attributable to common stock	$ (0.12)	$ (0.12)	$ (0.40)	$ (0.40)
Weighted average common shares outstanding, basic	24,911,908	21,266,639	24,301,045	21,265,247
Diluted loss per share attributable to common stock	$ (0.12)	$ (0.12)	$ (0.40)	$ (0.40)
Weighted average common shares outstanding, diluted	24,911,908	21,266,639	24,301,045	21,265,247
Comprehensive loss:				
Net loss	$(3,060,200)	$(2,459,072)	$ (9,715,269)	$(8,434,543)
Net unrealized gain (loss) on marketable investment securities	(2,656)	7,755	1,224	763

Comprehensive loss	$(3,062,856)	$(2,451,317)	$ (9,714,045)	$(8,433,780)

SOURCE Lipocine Inc.

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