Lipocine Announces Second Quarter 2019 Financial and Operational Results

SALT LAKE CITY, Aug. 7, 2019 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced financial results for the second quarter and six months ended June 30, 2019 and provided a corporate update.

Second Quarter and Recent Corporate Highlights

- Filed a New Drug Application ("NDA") for TLANDO™ as testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism.
    - The FDA has assigned November 9, 2019 as the Prescription Drug User Fee Act ("PDUFA") goal date.
- Received clearance from the U.S. Food and Drug Administration ("FDA") to clinically investigate LPCN 1144 in an expanded target population of adult male non-alcoholic steatohepatitis ("NASH") patients.
    - FDA has waived the limitation of only testing in NASH subjects with total testosterone levels below 300 ng/dL (threshold for hypogonadism).
- Initiated the *LiFT* ("Liver Fat intervention with oral Testosterone") LPCN 1144 Phase 2 clinical study, a paired-biopsy study in confirmed pre-cirrhotic NASH subjects.
- Filed suit against Clarus Therapeutics, Inc. ("Clarus") in the United States District Court ("Delaware") alleging that Clarus's JATENZO® product infringes six of Lipocine's U.S. patents.
- Joined the Russell Microcap® Index effective July 1, 2019 as a result of the Russell indexes annual reconstitution.

"During the second quarter, we continued to advance our pipeline, with important milestones achieved for both TLANDO and LPCN 1144," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. "The acceptance of the NDA for TLANDO for treating hypogonadism in males puts us on track for potential approval of this product in the fourth quarter of 2019. TLANDO is designed as a fixed dose oral TRT. For LPCN 1144, we were excited to initiate the *LiFT* study in biopsy confirmed NASH subjects, and based on our observed meaningful liver fat reduction in hypogonadal males, receive FDA clearance to expand our target patient population in adult NASH males regardless of their hypogonadal status. We believe this increases LPCN 1144's potential utility in a broader NASH population who reportedly have low testosterone."

Second Quarter Ended June 30, 2019 Financial Results

Lipocine reported a net loss of $3.4 million, or ($0.14) per diluted share, for the quarter ended June 30, 2019, compared with a net loss of $3.3 million, or ($0.15) per diluted share, in the quarter ended June 30, 2018.

Research and development expenses were $2.0 million for the quarter ended June 30, 2019, compared with $1.5 million for the quarter ended June 30, 2018. The increase in research and development expenses was primarily due to increases in outside service costs related to the second quarter initiation of the *LiFT* LPCN 1144 Phase 2 clinical study in confirmed pre-cirrhotic NASH subjects and increased contract research organization and outside consulting costs for TLANDO in connection with completion of the ABPM study and the filing of the NDA.

General and administrative expenses were $1.4 million for the quarter ended June 30, 2019, compared with $1.7 million for the quarter ended June 30, 2018. The decrease in general and administrative was primarily due to decreased personnel costs, a decrease in severance compensation, a decrease in stock compensation expense and a decrease in bonus expense. The decreases were offset by increases in other general and administrative expenses including an increase in professional fees, an increase in corporate insurance and an increase in marketing expenses.

As of June 30, 2019, the Company had total cash, cash equivalents and marketable securities aggregating $19.5 million, compared to $20.3 million at December 31, 2018. Of the total cash, cash equivalents and marketable securities balances, $5.0 million is restricted under our agreement with Silicon Valley Bank until TLANDO receives approval.

Six Months Ended June 30, 2019 Financial Results

Lipocine reported a net loss of $6.7 million, or ($0.28) per diluted share, for the six months ended June 30, 2019, compared with a net loss of $6.0 million, or ($0.28) per diluted share, in the six months ended June 30, 2018.

Research and development expenses were $3.9 million for the six months ended June 30, 2019, compared with $2.9 million for the six months ended June 30, 2018. The increase/decrease in research and development expenses was primarily due to increased 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 *LiFT* LPCN 1144 Phase 2 clinical study in confirmed pre-cirrhotic NASH subjects, increased outside contract research organization costs and sample storage costs related to TLANDO XR (LPCN 1111) offset by decreased contract manufacturing costs for LPCN 1107 and decreased personnel costs.

General and administrative expenses were $2.6 million for the six months ended June 30, 2019, compared with $3.4 million for the six months ended June 30, 2018. The decrease in general and administrative was primarily due to decreased personnel costs, which includes a decrease in salaries and related benefits mainly from the elimination of our commercial sales and marketing team in 2018, a decrease in severance compensation, a decrease in stock compensation expense and a decrease in bonus expense of $12,000. The decreases were offset by increases in other general and administrative expenses including an increase in professional fees and an increase 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 four development programs TLANDO, LPCN 1144, TLANDO XR (LPCN 1111) and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. LPCN 1144, an oral product of bioidentical testosterone, 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 is currently in Phase 2 testing. 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 product candidates and related clinical trials, the potential patient population for our product candidates, the timing of completion of clinical trials and expected FDA approvals, 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)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 3,664,319	$ 8,077,539
Restricted cash	5,000,000	5,000,000
Marketable investment securities	10,812,895	7,173,037

Accrued interest income	15,611	38,514
Prepaid and other current assets	148,930	520,113
Total current assets	19,641,755	20,809,203
Property and equipment, net of accumulated depreciation of $1,132,422 and $1,124,700, respectively	11,275	18,997
Other assets	23,753	23,753
Total assets	$ 19,676,783	$ 20,851,953
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 116,031	$ 671,280
Accrued expenses	993,456	487,135
Debt - current portion	3,333,333	3,333,333
Total current liabilities	4,442,820	4,491,748
Debt - non-current portion	5,383,757	6,926,532
Total liabilities	9,826,577	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; 24,729,700 and 21,737,196 issued and 24,723,990 and 21,731,486 outstanding	2,473	2,174
Additional paid-in capital	154,600,442	147,533,019
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive income (loss)	2,917	(963)
Accumulated deficit	(144,714,914)	(138,059,845)
Total stockholders' equity	9,850,206	9,433,673
Total liabilities and stockholders' equity	$ 19,676,783	$ 20,851,953

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenues:				
License revenue	$ -	$ -	$ -	$ 428,031
Total revenues	-	-	-	428,031
Operating expenses:				
Research and development	1,964,146	1,482,378	3,913,466	2,859,905
General and administrative	1,386,457	1,682,031	2,562,385	3,369,522
Total operating expenses	3,350,603	3,164,409	6,475,851	6,229,427
Operating loss	(3,350,603)	(3,164,409)	(6,475,851)	(5,801,396)

Other income (expense):				
Interest and investment income	124,581	120,403	249,846	230,585
Interest expense	(204,575)	(211,494)	(428,364)	(403,960)
Total other expense, net	(79,994)	(91,091)	(178,518)	(173,375)
Loss before income tax expense	(3,430,597)	(3,255,500)	(6,654,369)	(5,974,771)
Income tax expense	-	-	(700)	(700)
Net loss	$(3,430,597)	$(3,255,500)	$(6,655,069)	$(5,975,471)
Basic loss per share attributable to common stock	$ (0.14)	$ (0.15)	$ (0.28)	$ (0.28)
Weighted average common shares outstanding, basic	24,591,419	21,264,539	23,990,552	21,264,539
Diluted loss per share attributable to common stock	$ (0.14)	$ (0.15)	$ (0.28)	$ (0.28)
Weighted average common shares outstanding, diluted	24,591,419	21,264,539	23,990,552	21,264,539
Comprehensive loss:				
Net loss	$(3,430,597)	$(3,255,500)	$(6,655,069)	$(5,975,471)
Net unrealized gain (loss) on available-for-sale securities	1,528	8,043	3,880	(6,992)
Comprehensive loss	$(3,429,069)	$(3,247,457)	$(6,651,189)	$(5,982,463)

SOURCE Lipocine Inc.

For further information: Morgan Brown, Executive Vice President & Chief Financial Officer, (801) 994-7383, mb@lipocine.com; Investors, Hans Vitzthum, (617) 535-7743, hans@lifesciadvisors.com

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https://ir.lipocine.com/2019-08-07-Lipocine-Announces-Second-Quarter-2019-Financial-and-Operational-Results