Lipocine Announces First Quarter 2019 Financial and Operational Results

SALT LAKE CITY, May 8, 2019 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a specialty pharmaceutical company, today announced financial results for the quarter ended March 31, 2019, and provided a corporate update.

First Quarter and Recent Corporate Highlights

- Announced findings from the Ambulatory Blood Pressure Monitoring clinical study (NCT03868059) ("ABPM Study") designed to study TLANDO's effects on blood pressure. The results appear in line with recently approved testosterone replacement therapy.
- Announced top-line results from the 16-week Liver Fat Imaging Study ("Liver Fat Study") with LPCN 1144, designed to assess the therapeutic potential of LPCN 1144 in non-alcoholic steatohepatitis ("NASH"). Treatment results demonstrated that 48% of the treated subjects had NAFLD resolution at the end of the study. Additionally, 100% of the subjects experiencing NAFLD resolution had at least a 35% relative liver fat reduction from baseline with a relative mean liver fat reduction of 55% in this group.
- LPCN 1144 featured in late-breaker presentation at the EASL International Liver Conference, demonstrating reduction of liver fat (measured using magnetic resonance imaging, proton density fat fraction or "MRI-PDFF") and improvement in key serum biomarkers typically associated with NASH.
- Poster highlighting therapeutic potential of LPCN 1144 in NAFLD and NASH presented at ENDO 2019 meeting.
- Received clearance by the U.S. Food and Drug Administration ("FDA") for an Investigational New Drug ("IND") application to initiate a Phase 2 clinical study of LPCN 1144 in patients with biopsy confirmed NASH.
- Filed suit against Clarus Therapeutics, Inc. ("Clarus") in the United States District Court alleging that Clarus's JATENZO® product infringes six of Lipocine's U.S. patents.

"We achieved important milestones in Lipocine's most advanced clinical programs during the first quarter of 2019, and in recent weeks," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. Dr. Patel further stated, "With the successful completion of the ABPM study for TLANDO, we look forward to resubmitting our NDA for TLANDO in May 2019. We announced positive 16-week results from the Liver Fat Study of LPCN 1144 and have received clearance from the FDA to initiate a Phase 2 clinical study of LPCN 1144 in patients with biopsy confirmed NASH."

First Quarter Ended March 31, 2019 Financial Results

Lipocine reported a net loss of $3.2 million, or ($0.14) per diluted share, for the quarter ended March 31, 2019, compared with a net loss of $2.7 million, or ($0.13) per diluted share, in the quarter ended March 31, 2018.

Research and development expenses were $1.9 million for the quarter ended March 31, 2019, compared with $1.4 million for the quarter ended March 31, 2018. The increase in research and development expenses was primarily due to increased contract research organization costs for TLANDO in connection with the ABPM Study, offset by decreases in outside service costs primarily related to the January 2018 TLANDO BRUDAC meeting, decreases in contract manufacturing costs related to LPCN 1107, and decreases in personnel costs.

General and administrative expenses were $1.2 million for the quarter ended March 31, 2019, compared with $1.7 million for the quarter ended March 31, 2018. The decrease in general and administrative expenses was primarily due to decreased personnel costs, decreased professional fees offset by an increase in other administrative costs related to overhead.

As of March 31, 2019, the Company had unrestricted and restricted cash, cash equivalents and marketable securities aggregating $22.5 million, compared to $20.3 million at December 31, 2018. The $5.0 million of restricted cash, cash equivalents and marketable securities becomes unrestricted upon approval of TLANDO by the FDA.

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, LPCN 1111 and LPCN 1107. TLANDO, a novel oral prodrug of testosterone comprised of testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. LPCN 1144, an oral product of bioidentical testosterone comprised of testosterone undecanoate, recently completed a proof-of-concept clinical study demonstrating the potential utility in the treatment of NASH. 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 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)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 8,222,103	$ 8,077,539
Restricted cash	5,000,000	5,000,000
Marketable investment securities	9,300,338	7,173,037
Accrued interest income	16,369	38,514
Prepaid and other current assets	411,409	520,113
Total current assets	22,950,219	20,809,203
Property and equipment, net of accumulated depreciation of $1,128,561 and $1,124,700, respectively	15,136	18,997
Other assets	23,753	23,753
Total assets	$ 22,989,108	$ 20,851,953
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 517,725	$ 671,280
Accrued expenses	426,186	487,135
Debt - current portion	3,333,333	3,333,333
Total current liabilities	4,277,244	4,491,748
Debt - non-current portion	6,160,170	6,926,532
Total liabilities	10,437,414	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; 24,580,663 and 21,737,196 issued and 24,574,953 and 21,731,486 outstanding	2,458	2,174

Additional paid-in capital	153,872,876	147,533,019
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive income (loss)	1,389	(963)
Accumulated deficit	(141,284,317)	(138,059,845)
Total stockholders' equity	12,551,694	9,433,673
Total liabilities and stockholders' equity	$ 22,989,108	$ 20,851,953

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Revenues:		
License revenue	$ -	$ 428,031
Total revenues	-	428,031
Operating expenses:		
Research and development	1,949,321	1,377,527
General and administrative	1,175,927	1,687,490
Total operating expenses	3,125,248	3,065,017
Operating loss	(3,125,248)	(2,636,986)
Other income (expense):		
Interest and investment income	125,265	110,181
Interest expense	(223,789)	(192,466)
Total other expense, net	(98,524)	(82,285)
Loss before income tax expense	(3,223,772)	(2,719,271)
Income tax expense	(700)	(700)
Net loss	$ (3,224,472)	$ (2,719,971)
Basic loss per share attributable to common stock	$ (0.14)	$ (0.13)
Weighted average common shares outstanding, basic	23,383,008	21,264,539
Diluted loss per share attributable to common stock	$ (0.14)	$ (0.13)
Weighted average common shares outstanding, diluted	23,383,008	21,264,539
Comprehensive loss:		
Net loss	$ (3,224,472)	$ (2,719,971)
Net unrealized gain (loss) on available-for-sale securities	2,352	(15,035)
Comprehensive loss	$ (3,222,120)	$ (2,735,006)

SOURCE Lipocine Inc.

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