Lipocine Announces Financial and Operational Results for the Three and Nine Months Ended September 30, 2018

SALT LAKE CITY, Nov. 7, 2018 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a specialty pharmaceutical company, today announced financial results for the three and nine months ended September 30, 2018.

Third Quarter and Recent Corporate Highlights

- Completed enrollment of 138 subjects in the ongoing ambulatory blood pressure ("ABPM") clinical study 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 ABPM study is designed to address a deficiency identified in the FDA's Complete Response Letter ("CRL") issued May 2018. Results from the study are expected in the first quarter of 2019.
- Conducting a definitive phlebotomy study to evaluate the extent, if any, of clinically meaningful ex vivo conversion of testosterone undecanoate ("TU") to testosterone ("T") in serum blood collection tubes to confirm the reliability of TLANDO data results. Results are expected in the fourth quarter of 2018.
- Announced a late-breaking presentation highlighting LPCN 1144 data in potential non-alcoholic fatty liver disease ("NAFLD") / non-alcoholic steatohepatitis ("NASH") patients, at The Liver Meeting®, to take place in San Francisco November 9-13, 2018. The presentation will highlight data from multiple clinical trials of LPCN 1144 in potential NAFLD/NASH patients.
- Conducting a Proof-Of-Concept ("POC") study with LPCN 1144 in a biopsy-confirmed NASH in-vivo pre-clinical model. Results are expected in the first quarter of 2019.
- Completed enrollment of 36 subjects in the LPCN 1144 POC clinical study to assess liver fat changes in hypogonadal men at risk of developing non-alcoholic steatohepatitis ("NASH") using magnetic resonance imaging, proton density fat fraction ("MRI-PDFF") technique. Results are expected in the first quarter of 2019.

"We continue to believe there is a path forward for TLANDO and anticipate a resubmission of our NDA for TLANDO in the first half of 2019 based on results from on-going clinical studies," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. "We are also excited about our new product candidate, LPCN 1144, for NASH and look forward to receiving clinical trial results in the near term that will further support the use of an oral androgen for this important indication."

Three Months Ended September 30, 2018 Financial Results

Lipocine reported a net loss of $2.5 million, or ($0.12) per diluted share, for the three months ended September 30, 2018, compared with a net loss of $4.7 million, or ($0.22) per diluted share, for the three months ended September 30, 2017.

Research and development expenses were $1.4 million for the three months ended September 30, 2018, compared with $2.0 million for the three months ended September 30, 2017. The decrease in research and development expenses year over year was primarily due to reduced contract manufacturing organization costs for TLANDO and LPCN 1107 and reduced personnel costs, offset by increased contract research organization costs for TLANDO for the ABPM study. We expect research and development costs to increase through the first quarter of 2019 while we conduct the ABPM study for TLANDO and complete the POC liver imaging study for LPCN 1144.

General and administrative expenses were $930,000 for the three months ended September 30, 2018, compared with $2.7 million for the three months ended September 30, 2017. The decrease in general and administrative expenses year over year was primarily due to lower professional fees related to legal, intellectual property and commercial activities as well as decreased personnel costs related to reduced headcount.

As of September 30, 2018, the Company had unrestricted cash, cash equivalents, and marketable securities of $16.9 million, compared to cash, cash equivalents, and marketable securities of $21.5 million at December 31, 2017.

Nine Months Ended September 30, 2018 Financial Results

Lipocine reported a net loss of $8.4 million, or ($0.40) per diluted share, for the nine months ended September 30, 2018, compared with a net loss of $15.7 million, or ($0.80) per diluted share, in the nine months ended September 30, 2017.

Research and development expenses were $4.3 million for the nine months ended September 30, 2018, compared with $9.2 million for the nine months ended September 30, 2017. The decrease in research and development expenses year over year was primarily due to reduced contract research organization costs for TLANDO as the DV and DF studies were complete in 2017 while the ABPM study was being initiated in 2018, lower personnel costs, and lower contract manufacturing costs for LPCN 1107. This was offset by increased outside service and other costs primarily related to the Company's preparation for and participation in the meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee ("BRUDAC") of the FDA related to TLANDO that was held in January 2018.

General and administrative expenses were $4.3 million for the nine months ended September 30, 2018, compared with $6.6 million for the nine months ended September 30, 2017. The decrease in general and administrative expenses year over year was primarily due to decreased personnel costs related to reduced headcount. Additionally, professional fees related to legal, intellectual property and commercial activities also decreased in 2018.

About Lipocine

Lipocine Inc. is a specialty pharmaceutical company developing innovative pharmaceutical products for use in men's and women's health 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 containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. TLANDO received a Complete Response Letter from the FDA on May 8, 2018. LPCN 1144, an oral prodrug of bioidentical testosterone, is being developed as a treatment of non-alcoholic steatohepatitis ("NASH") and is currently being studied in two proof-of-concept clinical studies. 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 and the FDA review process relating to its product candidates, the timing of completion of clinical trials including the ABPM study for TLANDO as well as ongoing LPCN 1144 clinical trials, the path to approvability by the FDA of Lipocine's development programs, 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, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 4,802,806	$ 3,210,749
Restricted cash	5,000,000	-
Marketable investment securities	12,077,016	18,257,321
Accrued interest income	29,892	23,067
Litigation insurance recovery	-	3,319,927
Prepaid and other current assets	728,482	408,227
Total current assets	22,638,196	25,219,291
Property and equipment, net of accumulated depreciation of $1,120,256 and $1,121,080, respectively	23,442	75,070

Other assets	23,753	30,753
Total assets	$ 22,685,391	$ 25,325,114
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 239,922	$ 598,070
Litigation settlement payable	-	4,250,000
Accrued expenses	488,632	1,497,056
Debt - current portion	2,341,054	-
Total current liabilities	3,069,608	6,345,126
Debt - non-current portion	7,853,844	-
Total liabilities	10,923,452	6,345,126
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; 21,340,017 and 21,270,249 issued and 21,334,307 and 21,264,539 outstanding	2,134	2,127
Additional paid-in capital	146,638,736	145,423,012
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(3,853)	(4,616)
Accumulated deficit	(134,834,366)	(126,399,823)
Total stockholders' equity	11,761,939	18,979,988
Total liabilities and stockholders' equity	$ 22,685,391	$ 25,325,114

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
License revenue	$ -	$ -	$ 428,031	$ -
Total revenues	-	-	428,031	-
Operating expenses:				
Research and development	1,422,919	2,046,533	4,282,823	9,237,169
General and administrative	930,137	2,719,526	4,299,659	6,578,423
Total operating expenses	2,353,056	4,766,059	8,582,482	15,815,592
Operating loss	(2,353,056)	(4,766,059)	(8,154,451)	(15,815,592)
Other income (expense):				
Interest and investment income	112,561	65,811	343,145	165,018

Interest expense	(218,577)	-	(622,537)	-
Total other income (expense), net	(106,016)	65,811	(279,392)	165,018
Loss before income tax expense	(2,459,072)	(4,700,248)	(8,433,843)	(15,650,574)
Income tax expense	-	-	(700)	(700)
Net loss	$(2,459,072)	$(4,700,248)	$(8,434,543)	$ (15,651,274)
Basic loss per share attributable to common stock	$ (0.12)	$ (0.22)	$ (0.40)	$ (0.80)
Weighted average common shares outstanding, basic	21,266,639	20,890,580	21,265,247	19,666,131
Diluted loss per share attributable to common stock	$ (0.12)	$ (0.22)	$ (0.40)	$ (0.80)
Weighted average common shares outstanding, diluted	21,266,639	20,890,580	21,265,247	19,666,131
Comprehensive loss:				
Net loss	$(2,459,072)	$(4,700,248)	$(8,434,543)	$ (15,651,274)
Net unrealized gain on available-for-sale securities	7,756	79	763	7,960
Comprehensive loss	$(2,451,316)	$(4,700,169)	$(8,433,780)	$ (15,643,314)

SOURCE Lipocine Inc.

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