Lipocine Announces Financial and Operational Results for the Second Quarter and Six Months Ended June 30, 2018

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

Second Quarter and Recent Corporate Highlights

- Received a Complete Response Letter ("CRL") from the United States Food and Drug Administration ("FDA") regarding the New Drug Application ("NDA") 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.
- Dosed the first subject in the ambulatory blood pressure ("ABPM") clinical study for TLANDO. This study is being conducted to definitively characterize TLANDO's blood pressure effect, if any, and is expected to address the blood pressure related concern cited in the FDA's Complete Response Letter.
- Completed a Post Action Meeting with the FDA on July 19th in which the deficiencies raised in the CRL were discussed and a path forward for NDA resubmission for the potential approval of TLANDO was clarified. The FDA provided specific feedback on potential resolution of each deficiency, including clinical design elements where appropriate.

"We continue to believe that, as an oral drug, TLANDO offers significant benefits to hypogonadal patients compared to topical gels and injections. Following receipt of the CRL we remain committed to working with the FDA to arrive on a path forward for the potential approval of TLANDO," said Dr. Mahesh Patel, Chairman, President, and Chief Executive Officer of Lipocine. "We recently initiated an ambulatory blood pressure monitoring study, designed to address one of the concerns raised by the FDA, and we expect data from this study in the first quarter of 2019."

Second Quarter 2018 Financial Results

Lipocine reported a net loss of $3.3 million, or ($0.15) per diluted share, for the quarter ended June 30, 2018, compared with a net loss of $6.1 million, or ($0.31) per diluted share, in the quarter ended June 30, 2017.

Research and development expenses were $1.5 million in the quarter ended June 30, 2018, compared with $4.1 million in the quarter ended June 30, 2017. The decrease in research and development expenses was primarily due to reduced contract research organization costs related to on-going clinical development of TLANDO as well as less contract manufacturing costs in 2018.

General and administrative expenses were $1.7 million in the quarter ended June 30, 2018, compared with $2.0 million in the quarter ended June 30, 2017. The decrease in general and administrative expenses was primarily due to decreased professional fees in 2018 associated with legal, intellectual property and commercial activities as well as decreased personnel, office and overhead costs.

As of June 30, 2018, the Company had cash, cash equivalents, and marketable securities of $20.1 million, compared to cash, cash equivalents, and marketable securities of $21.5 million at December 31, 2017. Additionally, as of June 30, 2018 we had $5.0 million of restricted cash.

Six Months Ended June 30, 2018 Financial Results

Lipocine reported a net loss of $6.0 million, or ($0.28) per diluted share, for the six months ended June 30, 2018, compared with a net loss of $11.0 million, or ($0.58) per diluted share, in the six months ended June 30, 2017.

Research and development expenses were $2.9 million in the six months ended June 30, 2018, compared with $7.2 million in the six months ended June 30, 2017. The decrease in research and development expenses was primarily due to reduced contract research organization costs related to on-going clinical development of TLANDO, reduced personnel costs and less contract manufacturing costs for LPCN 1107 offset by an increase in outside services associated with the TLANDO BRUDAC meeting in January 2018.

General and administrative expenses were $3.4 million in the six months ended June 30, 2018, compared with $3.9 million in the six months ended June 30, 2017. The decrease in general and administrative expenses was primarily due to decreased personnel costs related to a reduced headcount in 2018. Additionally, professional

fees decreased in 2018 associated with legal, intellectual property and commercial activities as well as decreased office and overhead costs.

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 three development programs TLANDO, 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 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, 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)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 1,602,079	$ 3,210,749
Restricted cash	5,000,000	-
Marketable investment securities	18,488,756	18,257,321
Accrued interest income	46,687	23,067
Litigation insurance recovery	-	3,319,927
Prepaid and other current assets	113,250	408,227
Total current assets	25,250,772	25,219,291
Property and equipment, net of accumulated depreciation of $1,115,811 and $1,121,080, respectively	27,886	75,070
Other assets	23,753	30,753
Total assets	$ 25,302,411	$ 25,325,114
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 406,540	$ 598,070
Litigation settlement payable	-	4,250,000

Accrued expenses	886,980	1,497,056
Debt - current portion	1,549,485	-
Total current liabilities	2,843,005	6,345,126
Debt - non-current portion	8,580,447	-
Total liabilities	11,423,452	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; 21,270,249 and 21,270,249 issued and 21,264,539 and 21,264,539 outstanding	2,127	2,127
Additional paid-in capital	146,304,446	145,423,012
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(11,608)	(4,616)
Accumulated deficit	(132,375,294)	(126,399,823)
Total stockholders' equity	13,878,959	18,979,988
Total liabilities and stockholders' equity	$ 25,302,411	$ 25,325,114

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Revenues:				
License revenue	$ -	$ -	$ 428,031	$ -
Total revenues	-	-	428,031	-
Operating expenses:				
Research and development	1,482,378	4,106,897	2,859,905	7,190,636
General and administrative	1,682,032	2,033,721	3,369,522	3,858,897
Total operating expenses	3,164,410	6,140,618	6,229,427	11,049,533
Operating loss	(3,164,410)	(6,140,618)	(5,801,396)	(11,049,533)
Other income (expense):				
Interest and investment income	120,403	50,852	230,585	99,208
Interest expense	(211,494)	-	(403,960)	-
Total other income (expense), net	(91,091)	50,852	(173,375)	99,208
Loss before				

income tax expense	(3,255,501)	(6,089,766)	(5,974,771)	(10,950,325)
Income tax expense	-	-	(700)	(700)
Net loss	$ (3,255,501)	$ (6,089,766)	$ (5,975,471)	$ (10,951,025)
Basic loss per share attributable to common stock	$ (0.15)	$ (0.31)	$ (0.28)	$ (0.58)
Weighted average common shares outstanding, basic	21,264,539	19,372,625	21,264,539	19,043,759
Diluted loss per share attributable to common stock	$ (0.15)	$ (0.31)	$ (0.28)	$ (0.58)
Weighted average common shares outstanding, diluted	21,264,539	19,372,625	21,264,539	19,043,759
Comprehensive loss:				
Net loss	$ (3,255,501)	$ (6,089,766)	$ (5,975,471)	$ (10,951,025)
Net unrealized gain (loss) on available-for-sale securities	8,043	5,174	(6,992)	7,881
Comprehensive loss	$ (3,247,458)	$ (6,084,592)	$ (5,982,463)	$ (10,943,144)

SOURCE Lipocine Inc.

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