Lipocine Announces Financial and Operational Results for the First Quarter Ended March 31, 2018

SALT LAKE CITY, May 7, 2018 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a specialty pharmaceutical company, today announced financial results for the first quarter ended March 31, 2018.

First Quarter and Recent Corporate Highlights

- The Company received $10 million through a Loan and Security Agreement with Silicon Valley Bank ("SVB Loan").
- The Bone, Reproductive and Urologic Drugs Advisory Committee ("BRUDAC") of the U.S. Food and Drug Administration ("FDA") met to discuss the New Drug Application ("NDA") for TLANDO™, Lipocine's oral testosterone product candidate for the proposed indication of testosterone replacement therapy in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism.
    - BRUDAC voted six in favor and thirteen against the acceptability of the overall benefit/risk profile to support approval of TLANDO as a testosterone replacement therapy ("TRT").
- The Company and the other defendants entered into a memorandum of understanding to settle the purported securities class action litigation captioned *In re Lipocine Inc. Securities Litigation.*
- The Company initiated a phlebotomy clinical study under the TLANDO investigational new drug ("IND") Application to confirm no ex-vivo conversion of testosterone undecanoate to testosterone.
- The Company submitted a draft protocol for an ambulatory blood pressure monitoring ("ABPM") clinical study to the FDA for review under the TLANDO IND.
- The FDA's assigned Prescription Drug User Fee Act ("PDUFA") goal date for the TLANDO NDA is May 8, 2018.

"We look forward to learning the FDA outcome on our PDUFA goal date for TLANDO. We continue to believe that as an oral drug TLANDO offers significant benefits to patients compared to topical gels and injections. These benefits include overcoming the inadvertent testosterone transference risk to children and partners that exist with topical gels," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine.

First Quarter 2018 Financial Results

Lipocine reported a net loss of $2.7 million, or ($0.13) per diluted share, for the quarter ended March 31, 2018, compared with a net loss of $4.9 million, or ($0.26) per diluted share, in the quarter ended March 31, 2017.

License revenues were $428,000 during the three months ended March 31, 2018, compared to no revenue being received during the three months ended March 31, 2017. License revenue relates to royalty payments received from Spriaso, LLC under a licensing agreement for the cough and cold field.

Research and development expenses were $1.4 million in the quarter ended March 31, 2018, compared with $3.1 million in the quarter ended March 31, 2017. The decrease in research and development expenses was primarily due to reduced contract research organization costs for TLANDO and lower personnel costs offset by increased outside service costs primarily related to the TLANDO BRUDAC meeting in January 2018 and increased contract manufacturing costs for LPCN 1107.

General and administrative expenses were $1.7 million in the quarter ended March 31, 2018, compared with $1.8 million in the quarter ended March 31, 2017. The decrease in general and administrative expenses was primarily due to decreased personnel costs and overhead costs offset by increased professional fees related to legal, intellectual property and commercial activities.

As of March 31, 2018, the Company had cash, cash equivalents, and marketable securities of $27.8 million, compared to cash, cash equivalents, and marketable securities of $21.5 million at December 31, 2017. In the event TLANDO is not approved by the FDA on or prior to May 31, 2018, the SVB loan requires $5.0 million of cash to be restricted and held as cash collateral until such time as TLANDO is approved by the FDA.

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 was well tolerated and met the primary efficacy end-points in Phase 3 testing with twice daily dosing and is currently under FDA review. 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, is currently in Phase 2 testing and has been granted orphan drug designation by the FDA. 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 FDA review process relating to its product candidates, the expected timing of the FDA review process related to our resubmitted NDA, 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 that the FDA will determine there are deficiencies in our resubmitted NDA, 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)

Assets	March 31, 2018	December 31, 2017
Current assets:		
Cash and cash equivalents	$ 8,561,313	$ 3,210,749
Marketable investment securities	19,201,374	18,257,321
Accrued interest income	47,249	23,067
Litigation insurance recovery	3,566,649	3,319,927
Prepaid and other current assets	247,979	408,227
Total current assets	31,624,564	25,219,291
Property and equipment, net of accumulated depreciation of $1,111,366 and $1,121,080, respectively	32,331	75,070
Other assets	23,753	30,753
Total assets	$ 31,680,648	$ 25,325,114
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 388,356	$ 598,070
Litigation settlement payable	4,250,000	4,250,000
Accrued expenses	305,064	1,497,056
Debt - current portion	1,340,514	-
Total current liabilities	6,283,934	6,345,126
Debt - non-current portion	8,724,452	-
Total liabilities	15,008,386	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	145,850,292	145,423,012
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(19,651)	(4,616)
Accumulated deficit	(129,119,794)	(126,399,823)
Total stockholders' equity	16,672,262	18,979,988
Total liabilities and stockholders' equity	$ 31,680,648	$ 25,325,114

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ending March 31,	
	2018	**2017**
Revenues:		
License revenue	$ 428,031	$ -
Total revenues	428,031	-
Operating expenses:		
Research and development	1,377,527	3,083,739
General and administrative	1,687,490	1,825,176
Total operating expenses	3,065,017	4,908,915
Operating loss	(2,636,986)	(4,908,915)
Other income (expense):		
Interest and investment income	110,181	48,355
Interest expense	(192,466)	-
Total other income (expense), net	(82,285)	48,355
Loss before income tax expense	(2,719,271)	(4,860,560)
Income tax expense	(700)	(700)
Net loss	$(2,719,971)	$(4,861,260)
Basic loss per share attributable to common stock	$ (0.13)	$ (0.26)
Weighted average common shares outstanding, basic	21,264,539	18,711,239
Diluted loss per share attributable to common stock	$ (0.13)	$ (0.26)
Weighted average common shares outstanding, diluted	21,264,539	18,711,239
Comprehensive loss:		
Net loss	$(2,719,971)	$(4,861,260)
Net unrealized gain (loss) on available-for-sale securities	(15,035)	2,707
Comprehensive loss	$(2,735,006)	$(4,858,553)

SOURCE Lipocine Inc.

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