March 12, 2018

Lipocine Announces Financial and Operational Results for the Fiscal Year Ended December 31, 2017

SALT LAKE CITY, March 12, 2018 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a specialty pharmaceutical company, today announced financial results for the fourth quarter and fiscal year ended December 31, 2017.

Fourth Quarter and Recent Corporate Highlights

- On January 10, 2018, 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.
  - The Committee voted six in favor and thirteen against acceptability of overall benefit/risk profile to support approval of TLANDO as a Testosterone Replacement Therapy ("TRT").
  - Although the FDA will consider the recommendation of BRUDAC, the final decision regarding the approval of TLANDO is made by the FDA, and the recommendations by BRUDAC are non-binding.

"Although we are disappointed with the vote outcome of the BRUDAC, we believe the efficacy and safety of TLANDO are consistent with other FDA approved TRT products," said Dr. Mahesh Patel, Chairman, President, and Chief Executive Officer of Lipocine. "We are working with the FDA through the remainder of the review process and have submitted two clinical study protocols to the FDA for review. One protocol is for the conduct of an ambulatory blood pressure study and the second protocol is for the conduct of a phlebotomy study to assess the reliability of plain serum tubes for processing blood and obtaining testosterone measurements."

- The FDA's assigned Prescription Drug User Fee Act ("PDUFA") goal date for the TLANDO NDA is May 8, 2018.
- In January 2018, the Company received $10 million through a Loan and Security Agreement with Silicon Valley Bank.
- 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.*

Full Year 2017 Financial Results

Lipocine reported a net loss of $21.0 million, or ($1.05) per diluted share, for the year ended December 31, 2017, compared with a net loss of $19.0 million, or ($1.04) per diluted share, for the year ended December 31, 2016.

Research and development expenses were $11.0 million during the year ended December 31, 2017, compared with $8.1 million during the year ended December 31, 2016. The increase in research and development expenses was primarily due to increased contract research organization and consultant costs TLANDO related to the Dosing Validation ("DV") and Dosing Flexibility ("DF") clinical studies, increased contract manufacturing costs for LPCN 1107 and increased outside services expenses related to the Advisory Committee meeting for TLANDO. These increases were offset by decreased contract research organization costs for LPCN 1111, a decrease in validation and commercial batch manufacturing costs for TLANDO, and a decrease in contract research organization costs for LPCN 1107.

General and administrative expenses were $10.2 million during the year ended December 31, 2017, compared with $10.4 million during the year ended December 31, 2016. The decrease in general and administrative expenses during the year ended December 31, 2017 was primarily due to decreases in pre-commercialization marketing and sales activities related to TLANDO offset by an increase related to the class-action litigation settlement liability.

As of December 31, 2017, Lipocine had cash, cash equivalents, and marketable securities of $21.5 million, compared to cash, cash equivalents, and marketable securities of $26.8 million at December 31, 2016.

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 Lipocine's product candidates and its two new clinical study protocols, the expected timing of the FDA review process related to our resubmitted NDA for TLANDO, the impact of the BRUDAC recommendation on the FDA's decision process, 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
Consolidated Balance Sheets
December 31, 2017 and 2016
(unaudited)

	2017	2016
Assets		
Current assets:		
Cash and cash equivalents	$ 3,210,749	$ 5,560,716
Marketable investment securities	18,257,321	21,279,570
Accrued interest income	23,067	38,943
Litigation insurance recovery	3,319,927	-
Prepaid and other current assets	408,227	329,548
Total current assets	25,219,291	27,208,777
Property and equipment, net of accumulated depreciation of $1,121,080 and $1,092,710, respectively	75,070	103,440
Other assets	30,753	30,753
Total assets	$ 25,325,114	$ 27,342,970
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 598,070	$ 245,915
Litigation settlement payable	4,250,000	-

Accrued expenses	1,497,056	1,080,254
Total current liabilities	6,345,126	1,326,169
Total liabilities	6,345,126	1,326,169
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 18,462,325 issued and 21,264,539 and 18,456,615 outstanding	2,127	1,846
Additional paid-in capital	145,423,012	131,481,123
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(4,616)	(8,493)
Accumulated deficit	(126,399,823)	(105,416,963)
Total stockholders' equity	18,979,988	26,016,801
Total liabilities and stockholders' equity	$ 25,325,114	$ 27,342,970

LIPOCINE INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss
Years Ending December 31, 2017, 2016, and 2016
(unaudited)

	2017	2016	2015
Operating expenses:			
Research and development	$ 11,004,281	$ 8,076,053	$ 12,580,245
General and administrative	10,213,695	10,382,146	5,801,823
Restructuring costs	-	728,635	-
Total operating expenses	21,217,976	19,186,834	18,382,068
Operating loss	(21,217,976)	(19,186,834)	(18,382,068)
Other income, net	235,816	216,078	173,890
Loss before income tax expense	(20,982,160)	(18,970,756)	(18,208,178)
Income tax expense	(700)	(752)	(200)
Net loss	$ (20,982,860)	$(18,971,508)	$ (18,208,378)
Basic loss per share attributable to common stock	$ (1.05)	$ (1.04)	$ (1.11)
Weighted average common shares outstanding, basic	20,051,934	18,258,149	16,470,814
Diluted loss per share attributable to common stock	$ (1.05)	$ (1.04)	$ (1.11)
Weighted average common shares outstanding, diluted	20,051,934	18,258,149	16,470,814
Comprehensive loss:			
Net loss	$ (20,982,860)	$ (18,971,508)	$ (18,208,378)
Unrealized net gain (loss) on available-for-sale securities	3,877	24,407	(32,900)
Comprehensive loss	$ (20,978,983)	$(18,947,101)	$ (18,241,278)

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