Lipocine Announces Financial and Operational Results for the First Quarter 2017

SALT LAKE CITY, May 08, 2017 (GLOBE NEWSWIRE) --Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced financial results for the first quarter ended March 31, 2017.

First Quarter and Recent Corporate Highlights

• Announced completion of enrollment in both the dosing validation ("DV") and dosing flexibility ("DF") studies for LPCN 1021. LPCN 1021 is an oral testosterone product candidate for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone, also known as hypogonadism.

- Top-line results from both studies are expected in June 2017.
- Resubmission of the New Drug Application ("NDA") for LPCN 1021 is planned for the third quarter of 2017.

• Received additional guidance from the FDA regarding the pivotal Phase 3 clinical study design for LPCN 1107 which is being developed for reducing the risk of preterm birth ("PTB") in women with singleton pregnancy who have a history of singleton spontaneous PTB.

- Lipocine plans to submit the proposed Phase 3 protocol to the FDA via a Special Protocol Assessment ("SPA") in the second quarter of 2017.

• Promoted Gregory Bass to Executive Vice President and Chief Commercial Officer. Mr. Bass will be responsible for leading the commercialization of Lipocine's product candidates, including its testosterone replacement franchise.

"During 2017, we have made substantial progress in advancing our product candidates in preparation for upcoming data disclosures and planned regulatory filings," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine. "We plan to report top-line results from the on-going LPCN 1021 studies in June and expect to resubmit our NDA to the FDA in the third quarter of 2017. For LPCN 1107, we are preparing to submit the proposed Phase 3 trial design via an SPA in the second quarter of 2017."

First Quarter 2017 Financial Results

Lipocine reported a net loss of $4.9 million, or $0.26 per diluted share, for the first quarter ended March 31, 2017, compared with a net loss of $7.0 million, or $0.38 per diluted share, in the first quarter ended March 31, 2016.

Research and development expenses were $3.1 million in the first quarter of 2017, compared with $2.7 million in the first quarter of 2016. The change was primarily due to an increase in contract research organization costs in 2017 related to the on-going studies for LPCN 1021 offset by a decrease in manufacturing costs for LPCN 1021 as well as decrease in personnel costs as a result of our 2016 restructurings.

General and administrative expenses were $1.8 million in the first quarter of 2017, compared with $4.4 million in the first quarter of 2016. The change was primarily due to a decrease in business development, market research and pre-commercialization activities related to LPCN 1021 as well as decrease in personnel costs as a result of our 2016 restructurings.

As of March 31, 2016, Lipocine had cash, cash equivalents and marketable investment securities of $26.8 million, compared with cash and cash equivalents of $26.8 million as of 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 LPCN 1021, LPCN 1111 and LPCN 1107. LPCN 1021, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. LPCN 1021, was well tolerated and met the primary efficacy end-point in Phase 3 testing, which utilized 24-hour pharmacokinetic data for dose adjustments, and is currently being studied in two additional Phase 3 clinical trials. LPCN 1111, a novel oral prodrug of testosterone, originated with 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, the potentially first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth, 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, plans related to clinical trials, the possible outcome and timing of such clinical trials, the expected timing of clinical trial results or any related FDA review 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, advance regulatory developments and requirements, risks related to the FDA approval process, 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 Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ending March 31,	
	2017	**2016**
Operating expenses:		
Research and development	$ 3,083,739	$ 2,673,391
General and administrative	1,825,176	4,397,013
Total operating expenses	4,908,915	7,070,404
Operating loss	(4,908,915)	(7,070,404)
Other income, net	48,355	61,659
Loss before income tax expense	(4,860,560)	(7,008,745)
Income tax expense	(700)	(700)
Net loss	$ (4,861,260)	$ (7,009,445)
Basic loss per share attributable to common stock	$ (0.26)	$ (0.38)
Weighted average common shares outstanding, basic	18,711,239	18,251,905
Diluted loss per share attributable to common stock	$ (0.26)	$ (0.38)
Weighted average common shares outstanding, diluted	18,711,239	18,251,905
Comprehensive loss:		
Net loss	$ (4,861,260)	$ (7,009,445)
Net unrealized gain on available-for-sale securities	2,707	35,795
Comprehensive loss	$ (4,858,553)	$ (6,973,650)

LIPOCINE INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2017	**December 31, 2016**
Assets		
Current assets:		
Cash and cash equivalents	$ 6,936,511	$ 5,560,716
Marketable investment securities	19,860,549	21,279,570
Accrued interest income	35,946	38,943
Prepaid and other current assets	262,039	329,548
Total current assets	27,095,045	27,208,777
Property and equipment, net of accumulated depreciation of $1,099,803 and $1,092,710, respectively	96,347	103,440
Other assets	30,753	30,753
Total assets	$ 27,222,145	$ 27,342,970
Liabilities and Stockholders' Equity		

Current liabilities:		
Accounts payable	$ 853,510	$ 245,915
Accrued expenses	1,491,448	1,080,254
Total current liabilities	2,344,958	1,326,169
Total liabilities	2,344,958	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; 19,267,452 and 18,462,325 issued and 19,261,742 and 18,456,615 outstanding	1,927	1,846
Additional paid-in capital	135,199,981	131,481,123
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(5,786)	(8,493)
Accumulated deficit	(110,278,223)	(105,416,963)
Total stockholders' equity	24,877,187	26,016,801
Total liabilities and stockholders' equity	$ 27,222,145	$ 27,342,970

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