March 6, 2017

Lipocine Announces Financial and Operational Results for the Full Year of 2016

SALT LAKE CITY, March 06, 2017 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced financial and operational results for the full year ended December 31, 2016.

- Initiated both a Dosing Validation ("DV") Study and a Dosing Flexibility ("DF") Study for LPCN 1021, an oral testosterone product candidate for testosterone replacement therapy ("TRT") 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 projected in the second quarter of 2017.
- Received additional guidance regarding pivotal Phase 3 clinical study design from the FDA for LPCN 1107, a novel oral hydroxyprogesterone caproate ("HPC") product candidate that has been granted orphan drug designation by the FDA, in development for the proposed indication of reducing the risk of preterm birth ("PTB") in women with singleton pregnancy who have a history of singleton spontaneous PTB. The recent guidance received is in addition to feedback provided at the End of Phase 2 meeting with the FDA. Lipocine plans to submit the LPCN 1107 Phase 3 protocol to the FDA via a Special Protocol Assessment ("SPA") in the first half of 2017.

"During the quarter and subsequent period, we have made significant progress on the development of both LPCN 1021 and LPCN 1107," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine. "We currently expect this progress to continue in the near term, with top line results from our on-going LPCN 1021 studies and a SPA filing for LPCN 1107, both expected before mid-2017."

Full Year 2016 Financial Results

Lipocine reported a net loss of $19.0 million, or $1.04 per diluted share, for the full year of 2016, compared with a net loss of $18.2 million, or $1.11 per diluted share, for the full year of 2015.

For the full year of 2016, research and development expenses were $8.1 million, compared with $12.6 million for the full year of 2015. The change was primarily due to decreased contract research organization and consultant costs of $3.8 million. In addition, during the year ended December 31, 2015, we incurred a $2.3 million fee to file our NDA for LPCN 1021 with the FDA. These decreases in 2016 were offset by an increase in validation and commercial batch manufacturing costs for LPCN 1021 in 2016 of $1.7 million

For the full year of 2016, general and administrative expenses were $10.4 million, compared with $5.8 million for the full year of 2015. The change was primarily due an increase of $2.0 million in personnel costs due primarily to increased salaries and stock-based compensation related to a higher average headcount in 2016, an increase of $1.2 million for pre-commercialization marketing and sales activities related to LPCN 1021, and an increase of $750,000 in legal costs for class action defense and patent interference.

The full year of 2016 also included $0.7 million of restructuring costs.

As of December 31, 2016, Lipocine had cash, cash equivalents and marketable investment securities of $26.8 million, compared with cash and cash equivalents of $44.8 million as of December 31, 2015.

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
Consolidated Statements of Operations and Comprehensive Loss
Years Ending December 31, 2016, 2015 and 2014

	2016	2015	2014
Operating expenses:			
Research and development	$ 8,076,053	$ 12,580,245	$ 15,479,446
General and administrative	10,382,146	5,801,823	5,001,368
Restructuring costs	728,635	-	-
Total operating expenses	19,186,834	18,382,068	20,480,814
Operating loss	(19,186,834)	(18,382,068)	(20,480,814)
Other income, net	216,078	173,890	108,338
Loss before income tax expense	(18,970,756)	(18,208,178)	(20,372,476)
Income tax expense	(752)	(200)	(200)
Net loss	$ (18,971,508)	$ (18,208,378)	$ (20,372,676)
Basic loss per share attributable to common stock	$ (1.04)	$ (1.11)	$ (1.60)
Weighted average common shares outstanding, basic	18,258,149	16,470,814	12,766,295
Diluted loss per share attributable to common stock	$ (1.04)	$ (1.11)	$ (1.60)
Weighted average common shares outstanding, diluted	18,258,149	16,470,814	12,766,295
Comprehensive loss:			
Net loss	$ (18,971,508)	$ (18,208,378)	$ (20,372,676)
Unrealized net gain (loss) on available-for-sale securities	24,407	(32,900)	-
Comprehensive loss	$ (18,947,101)	$ (18,241,278)	$ (20,372,676)

LIPOCINE INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2016 and 2015

	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$ 5,560,716	$ 20,007,659
Marketable investment securities	21,279,570	24,375,168
Accrued interest income	38,943	144,536
Prepaid and other current assets	329,548	350,160
Total current assets	27,208,777	44,877,523
Property and equipment, net of accumulated depreciation of $1,092,710 and $1,060,750, respectively	103,440	75,750
Long-term marketable investment securities	-	400,252
Other assets	30,753	23,753
Total assets	$ 27,342,970	$ 45,377,278
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 245,915	$ 507,067
Accrued expenses	1,080,254	2,884,794
Total current liabilities	1,326,169	3,391,861
Total liabilities	1,326,169	3,391,861
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; 18,462,325 and 18,250,456 issued and 18,456,615 and 18,244,746 outstanding	1,846	1,825
Additional paid-in capital	131,481,123	128,502,659
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(8,493)	(32,900)
Accumulated deficit	(105,416,963)	(86,445,455)
Total stockholders' equity	26,016,801	41,985,417
Total liabilities and stockholders' equity	$ 27,342,970	$ 45,377,278

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