

Lipocine Announces Financial and Operational Results for the Second Quarter of 2016

SALT LAKE CITY, Aug. 09, 2016 (GLOBE NEWSWIRE) --[Lipocine Inc.](#) (NASDAQ:LPCN), a specialty pharmaceutical company, today announced financial and operational results for the quarter ended June 30, 2016.

Quarterly and Recent Highlights

- Received a Complete Response Letter ("CRL") from the United States Food and Drug Administration ("FDA") regarding its New Drug Application ("NDA") 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. The next step will be to request a meeting with the FDA to understand more fully the issues raised in the CRL and to agree on a path forward to achieve approval of LPCN 1021.
- Added to the Russell 3000® and Russell Global® Indexes.
- Presented clinical data for LPCN 1021 at the 2016 American Urological Association Annual Meeting.

"Our focus remains on evaluating the content of the CRL, including the FDA recommended actions, to bring our NDA for LPCN 1021 into a position for approval. We remain committed to bringing LPCN 1021 to patients who will benefit from its intended use," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine. "In addition, we continue to advance the progress of our other pipeline products, LPCN 1107 and LPCN 1111, with updates expected in the coming months."

Second Quarter 2016 Financial Results

Lipocine reported a net loss of \$5.8 million, or \$0.32 per diluted share, for the second quarter of 2016, compared with a net loss of \$4.2 million, or \$0.26 per diluted share, for the second quarter of 2015.

For the second quarter of 2016, research and development expenses were \$2.6 million, compared with \$3.2 million for the second quarter of 2015. The decrease was primarily due to decreased contract research organization and consultant costs, partially offset by increased pre-commercialization manufacturing expenses related to LPCN 1021.

For the second quarter of 2016, general and administrative expenses were \$3.2 million, compared with \$1.1 million for the second quarter of 2015. The increase was primarily due to increased costs related to business development, market research and pre-commercialization activities related to LPCN 1021 as well as increased personnel costs.

As of June 30, 2016, Lipocine had cash, cash equivalents and marketable investment securities of \$32.9 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. LPCN 1021, an oral testosterone replacement therapy product candidate, demonstrated positive efficacy and safety results in Phase 3 testing but received a Complete Response Letter from the FDA on June 28, 2016. LPCN 1111, a next-generation oral testosterone replacement therapy product with once-daily dosing, is currently in Phase 2 testing. LPCN 1107, which has the potential to become the first oral hydroxyprogesterone caproate product indicated for the prevention of recurrent preterm birth, has an End of Phase 2 meeting scheduled with the FDA during the third quarter of 2016 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 relating to Lipocine's FDA review process relating to LPCN 1021 and the possible outcome of such process, clinical trials, the regulatory process for our other product candidates, the potential uses and benefits of our product candidates, the TRT market, product development and commercialization efforts and the projected timing and outcome of regulatory filings and actions. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks related to our products, expected product benefits, clinical and regulatory expectations and plans, regulatory developments and requirements, risks related to the receipt of a CRL from the FDA for LPCN 1021, the receipt of regulatory approvals, the results of clinical trials, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine's products, the risks related to market conditions for Lipocine's common stock 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 June 30,		Six Months Ending June 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	\$ 2,567,701	\$ 3,161,908	\$ 5,241,092	\$ 5,080,603
General and administrative	3,247,419	1,115,835	7,644,432	2,171,379
Total operating expenses	5,815,120	4,277,743	12,885,524	7,251,982
Operating loss	(5,815,120)	(4,277,743)	(12,885,524)	(7,251,982)
Other income, net	55,009	31,297	116,668	49,930
Loss before income tax expense	(5,760,111)	(4,246,446)	(12,768,856)	(7,202,052)
Income tax expense	-	-	(700)	(200)
Net loss	<u>\$ (5,760,111)</u>	<u>\$ (4,246,446)</u>	<u>\$ (12,769,556)</u>	<u>\$ (7,202,252)</u>
Basic loss per share attributable to common stock	<u>\$ (0.32)</u>	<u>\$ (0.26)</u>	<u>\$ (0.70)</u>	<u>\$ (0.49)</u>
Weighted average common shares outstanding, basic	<u>18,251,683</u>	<u>16,496,239</u>	<u>18,251,794</u>	<u>14,667,943</u>
Diluted loss per share attributable to common stock	<u>\$ (0.32)</u>	<u>\$ (0.26)</u>	<u>\$ (0.70)</u>	<u>\$ (0.49)</u>
Weighted average common shares outstanding, diluted	<u>18,251,683</u>	<u>16,496,239</u>	<u>18,251,794</u>	<u>14,667,943</u>
Comprehensive loss:				
Net loss	\$ (5,760,111)	\$ (4,246,446)	\$ (12,769,556)	\$ (7,202,252)
Net unrealized gain (loss) on available-for-sale securities	3,051	(10,085)	38,846	(10,085)
Comprehensive loss	<u>\$ (5,757,060)</u>	<u>\$ (4,256,531)</u>	<u>\$ (12,730,710)</u>	<u>\$ (7,212,337)</u>

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

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,373,115	\$ 20,007,659
Marketable investment securities	20,565,077	24,375,168
Accrued interest income	104,902	144,536
Prepaid and other current assets	154,030	350,160
Total current assets	33,197,124	44,877,523
Property and equipment, net of accumulated depreciation of \$1,076,238 and \$1,060,750, respectively	119,912	75,750
Long-term marketable investment securities	-	400,252
Other assets	30,753	23,753
Total assets	<u>\$ 33,347,789</u>	<u>\$ 45,377,278</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 989,026	\$ 507,067
Accrued expenses	1,595,538	2,884,794
Total current liabilities	2,584,564	3,391,861
Total liabilities	<u>2,584,564</u>	<u>3,391,861</u>

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; 18,257,901 and 18,250,456 issued and 18,252,191 and 18,244,746 outstanding	1,825	1,825
Additional paid-in capital	130,011,177	128,502,659
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive income (loss)	5,946	(32,900)
Accumulated deficit	(99,215,011)	(86,445,455)
Total stockholders' equity	30,763,225	41,985,417
Total liabilities and stockholders' equity	<u>\$ 33,347,789</u>	<u>\$ 45,377,278</u>

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<https://ir.lipocine.com/Lipocine-Announces-Financial-and-Operational-Results-for-the-Second-Quarter-of-2016>