November 8, 2016

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

SALT LAKE CITY, Nov. 08, 2016 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced financial and operational results for the quarter ended September 30, 2016.

Quarterly and Recent Highlights

- Completed a Post Action meeting with the U.S. 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 purpose of the meeting was to review the previously received Complete Response Letter ("CRL") and to determine actions needed to achieve approval of LPCN 1021. Lipocine has submitted a new dosing validation clinical study protocol to the FDA and the FDA has agreed to review the protocol through a Special Protocol Assessment ("SPA").

- Reported positive top-line results from a Phase 2b clinical study of LPCN 1111, a novel oral TRT product candidate. The primary objectives of the study were to determine the Phase 3 dose of LPCN 1111 along with the safety and tolerability of LPCN 1111 and its metabolites following oral administration of single and multiple doses in hypogonadal males. Results of the Phase 2b study suggest that the primary objectives were met, including identifying the dose expected to be tested in a Phase 3 study. Good dose-response relationship was observed over the tested dose range in the Phase 2b study. The target Phase 3 dose met primary and secondary end points. LPCN 1111 was well tolerated with no drug-related severe or serious adverse events reported.

"We were pleased to have completed our Post Action meeting with the FDA, which we believe was very productive and identified a path to bring our NDA for LPCN 1021 into a position for approval, as we remained committed to the product," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine. "In addition, we continue to make substantial progress with both of our other pipeline products, most notably delivering positive clinical data for LPCN 1111 during the quarter."

Third Quarter 2016 Financial Results

The net loss for the third quarter of 2016 narrowed as compared with the net loss for the third quarter of 2015. Lipocine reported a net loss of $3.2 million, or $0.18 per diluted share, for the third quarter of 2016, compared with a net loss of $6.4 million, or $0.35 per diluted share, for the third quarter of 2015.

For the third quarter of 2016, research and development expenses were $1.5 million, compared with $4.7 million for the third quarter of 2015. The change was primarily due to decreased contract research organization and consultant costs as well as a $2.3 million fee paid in 2015 to file our NDA for LPCN 1021 with the FDA. These decreases were partially offset by an increase in validation and commercial batch manufacturing costs for LPCN 1021.

For the third quarter of 2016, general and administrative expenses were $1.4 million, compared with $1.7 million for the third quarter of 2015. The decrease was primarily due to decreased pre-commercialization marketing and sales activities related to LPCN 1021 partially offset by an increase in personnel costs.

As of September 30, 2016, Lipocine had cash, cash equivalents and marketable investment securities of $28.8 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 twice-daily oral testosterone replacement therapy product candidate, was well tolerated and met the primary efficacy end point in Phase 3 testing, which utilized 24-hour pharmacokinetic data for dose adjustments. LPCN 1111, a novel 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 was recently 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 FDA review process relating to LPCN 1021, the additional clinical trial needed to validate our dosing regimen and the FDA process with respect to our planned SPA, the possible outcome and timing of such clinical trial or FDA review process, the path to approvability by the FDA of LPCN 1021, our commitment to bring LPCN 1021 to market, the results of the Phase 2b clinical study of LPCN 1111, 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 LPCN 1021 or any of our other products, 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 and timing of clinical trials, including the additional clinical trial for LPCN 1021, 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 September 30,		Nine Months Ending September 30,	
	2016	**2015**	**2016**	**2015**
Operating expenses:				
Research and development	$ 1,506,581	$ 4,733,889	$ 6,747,673	$ 9,814,492
General and administrative	1,394,406	1,700,099	9,038,837	3,871,478
Restructuring costs	385,233	-	385,233	-
Total operating expenses	3,286,220	6,433,988	16,171,743	13,685,970
Operating loss	(3,286,220)	(6,433,988)	(16,171,743)	(13,685,970)
Other income, net	50,735	61,560	167,403	111,490
Loss before income tax expense	(3,235,485)	(6,372,428)	(16,004,340)	(13,574,480)
Income tax expense	-	-	(700)	(200)
Net loss	$ (3,235,485)	$ (6,372,428)	$ (16,005,040)	$ (13,574,680)
Basic loss per share attributable to common stock	$ (0.18)	$ (0.35)	$ (0.88)	$ (0.86)
Weighted average common shares outstanding, basic	18,252,681	18,238,632	18,252,092	15,871,252
Diluted loss per share attributable to common stock	$ (0.18)	$ (0.35)	$ (0.88)	$ (0.86)
Weighted average common shares outstanding, diluted	18,252,681	18,238,632	18,252,092	15,871,252
Comprehensive loss:				

Net loss	$ (3,235,485)	$ (6,372,428)	$ (16,005,040)	$ (13,574,680)
Net unrealized gain (loss) on available-for-sale securities	(5,824)	15,887	33,022	5,802
Comprehensive loss	$ (3,241,309)	$ (6,356,541)	$ (15,972,018)	$ (13,568,878)

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

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 4,706,639	$ 20,007,659
Marketable investment securities	24,132,453	24,375,168
Accrued interest income	115,205	144,536
Prepaid and other current assets	457,430	350,160
Total current assets	29,411,727	44,877,523
Property and equipment, net of accumulated depreciation of $1,084,474 and $1,060,750, respectively	111,676	75,750
Long-term marketable investment securities	-	400,252
Other assets	30,753	23,753
Total assets	$ 29,554,156	$ 45,377,278
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 864,951	$ 507,067
Accrued expenses	707,299	2,884,794
Total current liabilities	1,572,250	3,391,861
Total liabilities	1,572,250	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; 18,258,901 and 18,250,456 issued and 18,253,191 and 18,244,746 outstanding	1,826	1,825
Additional paid-in capital	130,471,165	128,502,659
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive income (loss)	122	(32,900)
Accumulated deficit	(102,450,495)	(86,445,455)
Total stockholders' equity	27,981,906	41,985,417
Total liabilities and stockholders' equity	$ 29,554,156	$ 45,377,278

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