Lipocine Announces Financial and Operational Results for the Full Year of 2015

SALT LAKE CITY, March 10, 2016 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced financial results for the full year ended December 31, 2015.

Quarterly and Recent Highlights

- Announced the acceptance of its 505(b)(2) New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") 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 FDA has assigned a Prescription Drug User Fee Act ("PDUFA") action date of June 28, 2016, for completion of the review of the NDA for LPCN 1021. Additionally, the 74-day filing communication letter did not mention a need to convene an Advisory Committee for advice on the NDA for LPCN 1021.

- Reported positive top-line results from its multi-dose pharmacokinetic ("PK") dose finding clinical study of LPCN 1107, an oral hydroxyprogesterone caproate ("HPC") product candidate for the prevention of preterm birth. Average steady state HPC levels ($C_{avg}0$-24) were comparable or higher for all three LPCN 1107 doses than for injectable HPC (Makena®). HPC levels as a function of daily dose were linear for the three LPCN 1107 doses. With all three LPCN 1107 doses tested, HPC exposure ($C_{avg}0$-24) did not fall below 6.4 ng/ml in any study subject, a level considered to be significant based on a previous literature study of injectable HPC[1]. LPCN 1107 was well tolerated across the three dose levels and no adverse drug reactions, serious adverse events or deaths were reported during the study.

- Initiated the Phase 2b clinical study for LPCN 1111, a novel TRT product candidate for hypogonadal males with potential for once-daily dosing. The study's primary objectives will be to determine the optimal dose, as well as the safety and tolerability, of LPCN 1111 and its metabolites following oral administration of single and multiple doses.

- Presented clinical data for LPCN 1021 at the 21st Annual Meeting of the Sexual Medicine Society of North America (SMSNA) in Las Vegas, NV.

"During 2015, Lipocine made significant progress across our entire portfolio of product candidates, highlighted by the filing of our NDA for LPCN1021 and subsequent FDA acceptance. As a novel oral therapy, we believe LPCN 1021 has the potential to address unmet needs in the testosterone replacement therapy marketplace," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine. "Looking forward, we expect 2016 to be a transformational period for Lipocine, with the LPCN 1021 PDUFA date in June and continued development of LPCN 1107 and LPCN 1111."

Full Year 2015 Financial Results

Lipocine reported a net loss of $18.2 million, or $1.11 per diluted share, for the full year of 2015, compared with a net loss of $20.4 million, or $1.60 per diluted share, for the full year of 2014.

For the full year of 2015, research and development expenses were $12.6 million, compared with $15.5 million for the full year of 2014. The decrease was largely attributable to decreased clinical research costs related to the completion of the Phase 3 clinical trial of LPCN 1021, partially offset by a one-time payment of $2.3 million to the FDA for the NDA filing.

For the full year of 2015, general and administrative expenses were $5.8 million, compared with $5.0 million for the full year of 2014. The increase was primarily due to increased personnel costs and costs related to market research and pre-commercialization activities.

As of December 31, 2015, Lipocine had cash, cash equivalents and marketable investment securities of $44.8 million, compared with cash and cash equivalents of $27.7 million as of December 31, 2014.

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 and has a New Drug Application under review with the FDA. 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, is currently in Phase 1 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 relating to Lipocine's common stock, the FDA review process relating to our product candidates and the possible outcome of such process, clinical trials, the potential uses and benefits of our product candidates, 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 FDA's review of our NDA 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.

[1]Caritis SN, Venkataramanan R, Thom E, et al. Relationship between 17-alpha hydroxyprogesterone caproate concentration and spontaneous preterm birth. Am J Obstet Gynecol 2014;210(2):128.

LIPOCINE INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss
Years Ending December 31, 2015 and 2014

	2015	2014
Operating expenses:		
Research and development	$ 12,580,245	$ 15,479,446
General and administrative	5,801,823	5,001,368
Total operating expenses	18,382,068	20,480,814
Operating loss	(18,382,068)	(20,480,814)
Other income, net	173,890	108,338
Loss before income tax expense	(18,208,178)	(20,372,476)
Income tax expense	(200)	(200)
Net loss	$ (18,208,378)	$ (20,372,676)
Basic loss per share attributable to common stock	$ (1.11)	$ (1.60)
Weighted average common shares outstanding, basic	16,470,814	12,766,295
Diluted loss per share attributable to common stock	$ (1.11)	$ (1.60)
Weighted average common shares outstanding, diluted	16,470,814	12,766,295
Comprehensive loss:		
Net loss	$ (18,208,378)	$ (20,372,676)
Unrealized net loss on available-for-sale securities	(32,900)	-
Comprehensive loss	$ (18,241,278)	$ (20,372,676)

LIPOCINE INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2015 and 2014

	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	$ 20,007,659	$ 27,666,055
Marketable investment securities	24,375,168	-
Accrued interest income	144,536	-
Prepaid and other current assets	350,160	229,912
Total current assets	44,877,523	27,895,967
Property and equipment, net of accumulated depreciation of $1,060,750 and $1,034,029, respectively	75,750	73,782
Long-term marketable investment securities	400,252	-
Other assets	23,753	23,753
Total assets	$ 45,377,278	$ 27,993,502
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 507,067	$ 306,276
Accrued expenses	2,884,794	1,327,256
Total current liabilities	3,391,861	1,633,532

Total liabilities	3,391,861	1,633,532
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; 18,250,456 and 12,800,382 issued and 18,244,746 and 12,794,672 outstanding	1,825	1,280
Additional paid-in capital	128,502,659	94,636,479
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(32,900)	-
Accumulated deficit	(86,445,455)	(68,237,077)
Total stockholders' equity	41,985,417	26,359,970
Total liabilities and stockholders' equity	$ 45,377,278	$ 27,993,502

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