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

SALT LAKE CITY, May 09, 2016 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced financial and operational results for the quarter ended March 31, 2016.

Quarterly and Recent Highlights

- Continued regulatory and pre-commercialization activities for LPCN 1021, branded as TLANDO™, 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. A 505(b)(2) New Drug Application ("NDA") has been submitted to the U.S. Food and Drug Administration ("FDA") and the FDA has assigned a Prescription Drug User Fee Act ("PDUFA") action date of June 28, 2016.

- 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 (Cavg0-24) were comparable or higher for all three LPCN 1107 doses than for the injectable HPC (Makena®). 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 TLANDO at the American Society of Andrology 41st Annual Conference, ENDO 2016 and the 2016 American Urological Association Annual Meeting.

"This is an exciting time in Lipocine's history as we approach the PDUFA date for TLANDO, a novel oral therapy, which we believe has the potential to address unmet needs in the testosterone replacement therapy marketplace," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine. "In the meantime, we continue to make significant progress with our other pipeline products, LPCN 1107 and LPCN 1111, as evidenced by the accomplishments in the quarter."

First Quarter 2016 Financial Results

Lipocine reported a net loss of $7.0 million, or $0.38 per diluted share, for the first quarter of 2016, compared with a net loss of $3.0 million, or $0.23 per diluted share, for the first quarter of 2015.

For the first quarter of 2016, research and development expenses were $2.7 million, compared with $1.9 million for the first quarter of 2015. The increase was primarily due to increased manufacturing expenses related to TLANDO and personnel costs, partially offset by decreased contract research organization and consultant costs related to the completion of the Phase 3 clinical trial of TLANDO.

For the first quarter of 2016, general and administrative expenses were $4.4 million, compared with $1.1 million for the first quarter of 2015. The increase was primarily due to increased costs related to business development, market research and pre-commercialization activities as well as increased personnel and litigation costs.

As of March 31, 2016, Lipocine had cash, cash equivalents and marketable investment securities of $38.2 million, compared with cash and cash equivalents of $44.8 million as of December 31, 2015.

About TLANDO

TLANDO is a novel twice-a-day oral testosterone replacement therapy product candidate that is designed to help restore normal testosterone levels in hypogonadal men. The safety and efficacy of TLANDO is currently under FDA review. Lipocine expects TLANDO will help fulfill an unmet need in the treatment of hypogonadism. The current testosterone market primarily uses short-acting injectable products as well as topical products that carry an FDA "black box" warning related to inadvertent transfer of testosterone to others. According to the IMS Health database, an average of half a million prescriptions a month have been dispensed so far in 2016 for TRT.

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. TLANDO, 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 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 TLANDO, 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 March 31,	
	2016	**2015**
Operating expenses:		
Research and development	$ 2,673,391	$ 1,918,695
General and administrative	4,397,013	1,055,544
Total operating expenses	7,070,404	2,974,239
Operating loss	(7,070,404)	(2,974,239)
Other income, net	61,659	18,633
Loss before income tax expense	(7,008,745)	(2,955,606)
Income tax expense	(700)	(200)
Net loss	$ (7,009,445)	$ (2,955,806)
Basic loss per share attributable to common stock	$ (0.38)	$ (0.23)
Weighted average common shares outstanding, basic	18,251,905	12,819,332
Diluted loss per share attributable to common stock	$ (0.38)	$ (0.23)
Weighted average common shares outstanding, diluted	18,251,905	12,819,332
Comprehensive loss:		
Net loss	$ (7,009,445)	$ (2,955,806)
Net unrealized gain on available-for-sale securities	$ 35,795	-
Comprehensive loss	$ (6,973,650)	$ (2,955,806)

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

Assets	**March 31, 2016**	**December 31, 2015**
Current assets:		
Cash and cash equivalents	$ 14,114,852	$ 20,007,659
Marketable investment securities	24,098,383	24,375,168
Accrued interest income	159,839	144,536
Prepaid and other current assets	268,857	350,160
Total current assets	38,641,931	44,877,523

Property and equipment, net of accumulated depreciation of $1,067,404 and $1,060,750, respectively	108,298	75,750
Long-term marketable investment securities	-	400,252
Other assets	23,753	23,753
Total assets	$ 38,773,982	$ 45,377,278
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,077,160	$ 507,067
Accrued expenses	1,916,604	2,884,794
Income taxes payable	700	-
Total current liabilities	2,994,464	3,391,861
Total liabilities	2,994,464	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; 18,256,901 and 18,250,456 issued and 18,251,191 and 18,244,746 outstanding	1,825	1,825
Additional paid-in capital	129,270,410	128,502,659
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive income (loss)	2,895	(32,900)
Accumulated deficit	(93,454,900)	(86,445,455)
Total stockholders' equity	35,779,518	41,985,417
Total liabilities and stockholders' equity	$ 38,773,982	$ 45,377,278

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