Lipocine Announces Financial and Operational Results for the First Quarter of 2015

SALT LAKE CITY, May 7, 2015 (GLOBE NEWSWIRE) -- Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, today announced financial results for the quarter ended March 31, 2015, as well as recent operational highlights.

Quarterly and Recent Highlights

- Completed the last patient visit in the safety assessment portion of its Study of Oral Androgen Replacement ("SOAR") pivotal Phase 3 clinical study (http://clinicaltrials.gov/show/NCT02081300) evaluating efficacy and safety of LPCN 1021, its Oral Testosterone product for hypogonadal men with low testosterone. Lipocine previously announced positive top line efficacy from the SOAR clinical study in September 2014 and expects to announce top-line results from the 52 week safety assessment portion of the SOAR clinical study by mid-year, as well as file the New Drug Application ("NDA") with the U.S. Food and Drug Administration in the second half of this year.
- Completed an underwritten public offering of 5,347,500 shares of its common stock at $6.50 per share for gross proceeds of $34.8 million. Lipocine received net proceeds of approximately $32.5 million, after deducting the underwriters' discounts and other estimated offering expenses.
- Completed its pre-NDA meeting with the U.S. Food and Drug Administration ("FDA") related to LPCN 1021. Based on the FDA's preliminary response, Lipocine does not expect to conduct any additional clinical studies other than the on-going labeling "food effect" study which has always been required for the expected submission of the NDA. Lipocine is conducting the labeling "food effect" study per the FDA requirement and plans to submit preliminary results from this study to the FDA in the second quarter of 2015 for review and comment prior to submitting the NDA.
- Presented additional data from its ongoing SOAR pivotal Phase 3 clinical study evaluating efficacy and safety of LPCN 1021 at both the American Society of Andrology 40th Annual Conference in Salt Lake City, Utah and the ENDO 2015 in San Diego, CA.
- Announced successful top-line results of a Phase 1b study of LPCN 1107, its oral hydroxyprogesterone caproate ("HPC") product candidate. Results from this study demonstrated significant HPC absorption following oral administration in healthy pregnant women. In this study, LPCN 1107 was well tolerated with no serious adverse events observed. Lipocine has requested a meeting with the FDA and expects to provide guidance on the development plan for LPCN 1107 in the second quarter of 2015.
- Presented data from a successful Phase 1a study of LPCN 1107 at the Society for Maternal-Fetal Medicine 35th Annual Meeting in San Diego, CA. The study was designed to determine the pharmacokinetics and bioavailability of LPCN 1107 relative to an intramuscular (IM) HPC, as well as safety and tolerability, in healthy non-pregnant female volunteers.
- Completed a Phase 2a clinical study of LPCN 1111, a next-generation novel testosterone TRT product candidate, in hypogonadal males with Low T. Based on these positive results, a Phase 2b study is expected to begin in the fourth quarter of 2015 or the first quarter of 2016 with the objective of determining the optimal once daily dosing regimen of LPCN 1111.

"The beginning of 2015 has been an eventful period for Lipocine, with FDA interaction, multiple data presentations and continued progress with our lead product, LPCN 1021, and our other clinical programs," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "In addition, the recent completion of our public offering has strengthened our balance sheet and provides us with the necessary capital to accelerate development of our earlier clinical assets."

First Quarter 2015 Financial Results

Lipocine reported a net loss of $3.0 million, or $0.23 per diluted share, for the first quarter of 2015, compared with a net loss of $5.3 million, or $0.41 per diluted share, for the first quarter of 2014.

For the first quarter of 2015, research and development expenses were $1.9 million, compared with $3.4 million for the first quarter of 2014. The decrease was largely attributable to decreased external service provider costs related to clinical research and contract manufacturing and also reduced internal personnel costs.

For the first quarter of 2015, general and administrative expenses were $1.1 million, compared with $1.9 million for the same period in 2014. The decrease was primarily due to accelerated vesting and extension of exercise dates from retiring directors in the 2014 period and also reduced legal and accounting fees. This was partially offset by a slight increase in other personnel costs.

As of March 31, 2015, Lipocine had cash and cash equivalents of $24.8 million, compared with cash and cash equivalents of $27.7 million as of December 31, 2014. This does not include the net proceeds of $32.5 million from the public offering we completed on April 29, 2015, as this occurred subsequent to the quarter end.

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 lead product candidate, LPCN 1021, demonstrated positive top-line efficacy results in Phase 3 testing and is targeted for testosterone replacement therapy, or TRT. Additional pipeline candidates include LPCN 1111, a next generation oral testosterone therapy product with once daily dosing, that is currently in Phase 2 testing, and LPCN 1107, which has the potential to become the first oral hydroxyprogesterone caproate (HPC) product indicated for the prevention of recurrent preterm birth, is currently in Phase 1 testing.

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 an underwritten public offering of Lipocine's common stock, clinical trials, the potential uses and benefits of Lipocine's product candidates, and product development and commercialization efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks related to market conditions for

Lipocine's common stock, the failure to satisfy offering conditions, the risks related to the receipt of regulatory approvals, the results 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 and the final prospectus supplement which will be filed with the SEC, 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,	
	2015	**2014**
Operating expenses:		
Research and development	$ 1,918,695	$ 3,368,999
General and administrative	1,055,544	1,923,623
Total operating expenses	2,974,239	5,292,622
Operating loss	(2,974,239)	(5,292,622)
Other income, net	18,633	25,466
Loss before income tax expense	(2,955,606)	(5,267,156)
Income tax expense	(200)	--
Net loss	$ (2,955,806)	$ (5,267,156)
Basic loss per share attributable to common stock	$ (0.23)	$ (0.41)
Weighted average common shares outstanding, basic	12,819,332	12,728,086
Diluted loss per share attributable to common stock	$ (0.23)	$ (0.41)
Weighted average common shares outstanding, diluted	12,819,332	12,728,086
Comprehensive loss	$ (2,955,806)	$ (5,267,156)

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

(Unaudited)

	March 31, 2015	**December 31, 2014**
Assets		
Current assets:		
Cash and cash equivalents	$ 24,764,456	$ 27,666,055
Prepaid and other current assets	186,462	229,912
Total current assets	24,950,918	27,895,967
Property and equipment, net of accumulated depreciation of $1,038,332 and $1,034,029, respectively	82,709	73,782
Other assets	23,753	23,753
Total assets	$ 25,057,380	$ 27,993,502
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 379,528	$ 306,276
Accrued expenses	957,777	1,327,256
Total current liabilities	1,337,305	1,633,532
Total liabilities	1,337,305	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; 12,850,090 and 12,800,382 issued and 12,844,380 and 12,794,672 outstanding	1,285	1,280
Additional paid-in capital	94,952,385	94,636,479
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated deficit	(71,192,883)	(68,237,077)
Total stockholders' equity	23,720,075	26,359,970
Total liabilities and stockholders' equity	$ 25,057,380	$ 27,993,502

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