Lipocine Announces Financial and Operational Results for the Second Quarter and Six Months Ended June 30, 2017

SALT LAKE CITY, Aug. 07, 2017 (GLOBE NEWSWIRE) --Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced financial results for the three and six months ended June 30, 2017.

Second Quarter and Recent Corporate Highlights

• Announced results from the dosing validation ("DV") and dosing flexibility ("DF") studies evaluating efficacy and tolerability of LPCN 1021. Although there is no guarantee of U.S. Food and Drug Administration ("FDA") approval, the positive results from the DV study confirms the validity of a fixed dose approach without the need for dose titration to orally administering LPCN 1021.

- LPCN 1021 successfully met the FDA primary efficacy guidelines in the DV study in which 80% of the subjects using baseline observation carried forward ("BOCF") achieved average testosterone levels within the normal range with a lower bound confidence interval of 72%.
- The results from the DV study confirmed that twice daily dosing is the appropriate dosing regimen for LPCN 1021 and will be the basis for resubmission.
- LPCN 1021 generally met the pre-specified per dose secondary endpoints for twice daily oral administration.
- All drug related adverse events were either mild or moderate in intensity and none were severe. To date, the safety database of LPCN 1021 demonstrates a profile consistent with other TRT products.
- Currently on track to resubmit a New Drug Application ("NDA") to FDA in the August 2017.

• Submitted a Special Protocol Assessment ("SPA") request to the FDA as part of the ongoing interaction with agency on the detailed design of the planned Phase 3 clinical development program for LPCN 1107 for prevention of recurrent preterm birth ("PTB") with history of singleton pregnancy.

- The proposed Phase 3 clinical trial is designed as an adequate and well-controlled non-inferiority trial comparing LPCN 1107 with Makena®, the current standard of care for PTB.
- Based on prior interactions with the FDA, Lipocine has proposed an efficacy endpoint focusing on the rate of delivery at less than 37 weeks gestation. Success on this gestational age endpoint could lead to Subpart H approval by the FDA.

• Initiated a preclinical toxicology study with LPCN 1111, our next generation oral testosterone replacement therapy with potential for once-daily dosing therapy.

- Upon completion of the preclinical toxicology study, Lipocine plans to meet with the FDA for an End of Phase 2 meeting.

"We are pleased with our accomplishments and progress in the second quarter with LPCN 1021 and LPCN 1111, our oral testosterone replacement therapies, and LPCN 1107, our oral alternative for the prevention of preterm birth," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. "We believe that the data from the DV study validates our 'no titration' dosing regimen and addresses the FDA concerns identified in our Complete Response Letter. We are targeting NDA resubmission during August 2017 and consider LPCN 1021 to be a differentiated TRT option for treating hypogonadism in men with the potential to both improve patient compliance and eliminate the risk of testosterone transference."

Second Quarter Ended June 30, 2017 Financial Results

Lipocine reported a net loss of $6.1 million, or ($0.31) per diluted share, for the second quarter ended June 30, 2017, compared with a net loss of $5.8 million, or ($0.32) per diluted share, in the second quarter ended June 30, 2016.

Research and development expenses were $4.1 million in the second quarter ended June 30, 2017, compared with $2.6 million in the second quarter ended June 30, 2016. The increase in research and development expenses year over year was primarily due to an increase in contract research organization costs of $2.3 million for LPCN 1021 for the conduct of the DV and the DF clinical studies offset by a decrease in technical batch manufacturing costs for LPCN 1021 of $747,000 and decreased personnel costs of $26,000. Personnel costs decreased as a result of the restructurings that took place in July 2016 and October 2016.

General and administrative expenses were $2.0 million in the second quarter ended June 30, 2017, compared with $3.2 million in the second quarter ended June 30, 2016. The decrease in general and administrative expenses year over year was primarily due to a decrease of $1.0 million for business development, market research and pre-commercialization activities related to LPCN 1021, as well as decreases in travel and personnel costs. Personnel costs decreased as a result of the restructurings that took place in July 2016 and October 2016.

As of June 30, 2016, Lipocine had cash, cash equivalents and marketable investment securities of $27.8 million, compared with cash and cash equivalents of $26.8 million as of December 31, 2016.

Six Months Ended June 30, 2017 Financial Results

Lipocine reported a net loss of $11.0 million, or ($0.58) per diluted share, for the six months ended June 30, 2017, compared with a net loss of $12.8 million, or ($0.70) per diluted share, in the six-month period ended June 30, 2016.

Research and development expenses were $7.2 million in the six months ended June 30, 2017, compared with $5.2 million in the six months ended June 30, 2016. The increase in research and development expenses in the six months ended June 30, 2017 was primarily due to an increase in contract research organization costs of $3.7 million for LPCN 1021 for the conduct of the DV and DF clinical studies offset by a decrease in technical batch manufacturing costs for LPCN 1021 of $1.5 million and decreased personnel costs.

General and administrative expenses were $3.9 million in the six months ended June 30, 2017, compared with $7.6 million in the six months ended June 30, 2016. The decrease year over year was primarily due to a decrease of $2.0 million for business development, market research and pre-commercialization activities related to LPCN 1021, as well as decreases in legal fees related to patent litigation, travel expenses and personnel costs.

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 novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. LPCN 1021 was well tolerated and met the primary efficacy end-points in Phase 3 testing with twice daily dosing. LPCN 1111, a novel oral prodrug of testosterone, originated 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 is potentially the first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth and has been granted orphan drug designation by the FDA. An End of Phase 2 meeting with the FDA has been 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 product candidates and related clinical trials and the FDA review process relating to its product candidates, plans related to clinical trials, the possible outcome and timing of such clinical trials, the expected timing of clinical trial results or any related FDA review process, the path to approvability by the FDA of Lipocine's development programs, 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 any of our products, risks related to our products, expected product benefits not being realized, clinical and regulatory expectations and plans not being realized, advance regulatory developments and requirements, risks related to the FDA approval process, the receipt of regulatory approvals, the results and timing 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, 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,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 4,106,897	$ 2,567,701	$ 7,190,636	$ 5,241,092
General and administrative	2,033,721	3,247,419	3,858,897	7,644,432
Total operating expenses	6,140,618	5,815,120	11,049,533	12,885,524
Operating loss	(6,140,618)	(5,815,120)	(11,049,533)	(12,885,524)
Other income, net	50,852	55,009	99,208	116,668
Loss before income tax expense	(6,089,766)	(5,760,111)	(10,950,325)	(12,768,856)
Income tax expense	-	-	(700)	(700)
Net loss	$ (6,089,766)	$ (5,760,111)	$ (10,951,025)	$ (12,769,556)
Basic loss per share attributable to common stock	$ (0.31)	$ (0.32)	$ (0.58)	$ (0.70)
Weighted average common shares outstanding, Basic	19,372,625	18,251,683	19,043,759	18,251,794
Diluted loss per share attributable to common stock	$ (0.31)	$ (0.32)	$ (0.58)	$ (0.70)
Weighted average common shares outstanding, diluted	19,372,625	18,251,683	19,043,759	18,251,794

Comprehensive loss:				
Net loss	$ (6,089,766)	$ (5,760,111)	$ (10,951,025)	$ (12,769,556)
Net unrealized gain on available-for-sale securities	5,174	3,051	7,881	38,846
Comprehensive loss	$ (6,084,592)	$ (5,757,060)	$ (10,943,144)	$ (12,730,710)

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

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 16,631,174	$ 5,560,716
Marketable investment securities	11,194,270	21,279,570
Accrued interest income	13,479	38,943
Prepaid and other current assets	88,638	329,548
Total current assets	27,927,561	27,208,777
Property and equipment, net of accumulated depreciation of $1,106,895 and $1,092,710, respectively	89,255	103,440
Other assets	30,753	30,753
Total assets	$ 28,047,569	$ 27,342,970
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,113,789	$ 245,915
Accrued expenses	1,786,150	1,080,254
Total current liabilities	2,899,939	1,326,169
Total liabilities	2,899,939	1,326,169
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; 20,587,308 and 18,462,325 issued and 20,581,598 and 18,456,615 outstanding	2,059	1,846
Additional paid-in capital	141,554,883	131,481,123
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(612)	(8,493)
Accumulated deficit	(116,367,988)	(105,416,963)
Total stockholders' equity	25,147,630	26,016,801
Total liabilities and stockholders' equity	$ 28,047,569	$ 27,342,970

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