Lipocine Investor Room

Lipocine Announces Financial and Operational Results for the Third Quarter and Nine Months Ended September 30, 2017

SALT LAKE CITY, Nov. 08, 2017 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced financial results for the three and nine months ended September 30, 2017.

Third Quarter and Recent Corporate Highlights

- Resubmitted a New Drug Application ("NDA") for TLANDO™, Lipocine's oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism.
    - The U.S. Food & Drug Administration ("FDA") acknowledged receipt of the Company's NDA resubmission for TLANDO, and assigned a new Prescription Drug User Fee Act ("PDUFA") action goal date of February 8, 2018.
    - The FDA scheduled a Bone, Reproductive and Urologic Drugs Advisory Committee ("BRUDAC") meeting on January 10, 2018 to discuss the NDA for TLANDO.
    - The NDA includes the efficacy results of a dosing validation ("DV") study, which confirmed the validity of a fixed dose approach to orally administer TLANDO without the need for dose titration, as well as an integrated safety set ("ISS") from all previously conducted clinical trials, including 52-week safety results from the Phase 3 Study of Androgen Replacement ("SOAR") clinical study.

"We accomplished all of our goals for the third quarter, culminating in the resubmission and acceptance of the NDA for TLANDO by the FDA," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. "TLANDO has the potential to be the first oral TRT option for patients and, if approved, will address a large and growing unmet medical need. We are preparing our presentation package for BRUDAC and look forward to discussing our NDA with the Advisory Committee in January 2018."

Third Quarter Ended September 30, 2017 Financial Results
Lipocine reported a net loss of $4.7 million, or ($0.22) per diluted share, for the third quarter ended September 30, 2017, compared with a net loss of $3.2 million, or ($0.18) per diluted share, in the third quarter ended September 30, 2016.

Research and development expenses were $2.0 million in the third quarter ended September 30, 2017, compared with $1.5 million in the third quarter ended September 30, 2016. The increase in research and development expenses was primarily due to an increase in contract research organization costs associated with the DV and Dosing Flexibility ("DF") clinical studies and an increase in contract manufacturing costs for LPCN 1107, offset by a decrease in travel and other allocated overhead costs.

General and administrative expenses were $2.7 million in the third quarter ended September 30, 2017, compared with $1.4 million in the third quarter ended September 30, 2016. The increase in was primarily due to an increase in market research and pre-commercialization activities related to TLANDO and an increase in personnel costs including accelerated vesting of stock options and restricted stock units related to a terminated employee.

As of September 30, 2017, the Company had $25.7 million of cash, cash equivalents and marketable investment securities compared to $26.8 million at December 31, 2016.

Nine Months Ended September 30, 2017 Financial Results
Lipocine reported a net loss of $15.7 million, or ($0.80) per diluted share, for the nine months ended September 30, 2017, compared with a net loss of $16.0 million, or ($0.88) per diluted share, in the nine-month period ended September 30, 2016.

Research and development expenses were $9.2 million in the nine months ended September 30, 2017, compared with $6.7 million in the nine months ended September 30, 2016. The increase in the nine months ended September 30, 2017 was primarily due to an increase in contract research organization costs related to the DV and DV clinical studies offset by a decrease in technical batch manufacturing costs for TLANDO, decreased personnel costs, decreased outside services costs and reduced travel and other allocated overhead costs.

General and administrative expenses were $6.6 million in the nine months ended September 30, 2017, compared with $9.0 million in the nine months ended September 30, 2016. The decrease in general and administrative expenses during the nine months ended September 30, 2017 was primarily due to a decrease in business development, market research and pre-commercialization activities related to TLANDO, a decrease in legal fees related to patent litigation, and a decrease in 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 TLANDO, LPCN 1111 and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. TLANDO was well tolerated and met the primary efficacy end-points in Phase 3 testing with twice daily dosing and is currently under FDA review. 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, the expected timing of the FDA review process related to our resubmitted NDA, 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, the risk that BRUDAC may make a negative recommendation to the Commissioner of the FDA with respect to TLANDO, risks related to our products, expected product benefits not being realized, clinical and regulatory expectations and plans not being realized, new regulatory developments and requirements, risks related to the FDA approval process including that the FDA will determine there are deficiencies in our resubmitted NDA, 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.

CONTACT:
Morgan Brown
Executive Vice President & Chief Financial Officer
Phone: (801) 994-7383
mb@lipocine.com

Investors:
Hans Vitzthum
Phone: (646) 597-6979
hans@lifesciadviors.com

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

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 9,270,823	$ 5,560,716
Marketable investment securities	16,408,750	21,279,570
Accrued interest income	9,256	38,943
Prepaid and other current assets	453,446	329,548
Total current assets	26,142,275	27,208,777
Property and equipment, net of accumulated depreciation of $1,113,988 and $1,092,710, respectively	82,162	103,440
Other assets	30,753	30,753
Total assets	$ 26,255,190	$ 27,342,970
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 803,819	$ 245,915
Accrued expenses	1,680,315	1,080,254
Total current liabilities	2,484,134	1,326,169

Total liabilities	2,484,134	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; 21,185,817 and 18,462,325 issued and 21,180,107 and 18,456,615 outstanding	2,119	1,846
Additional paid-in capital	144,878,419	131,481,123
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(533)	(8,493)
Accumulated deficit	(121,068,237)	(105,416,963)
Total stockholders' equity	23,771,056	26,016,801
Total liabilities and stockholders' equity	$ 26,255,190	$ 27,342,970

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ending September 30,		Nine Months Ending September 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 2,046,533	$ 1,506,581	$ 9,237,169	$ 6,747,673
General and administrative	2,719,526	1,394,406	6,578,423	9,038,837
Restructuring costs	-	385,233	-	385,233
Total operating expenses	4,766,059	3,286,220	15,815,592	16,171,743
Operating loss	(4,766,059)	(3,286,220)	(15,815,592)	(16,171,743)
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Other income, net	65,811	50,735	165,018	167,403
Loss before income tax expense	(4,700,248)	(3,235,485)	(15,650,574)	(16,004,340)
Income tax expense	-	-	(700)	(700)
Net loss	$ (4,700,248)	$ (3,235,485)	$ (15,651,274)	$ (16,005,040)
Basic loss per share attributable to common stock	$ (0.22)	$ (0.18)	$ (0.80)	$ (0.88)
Weighted average common shares outstanding, basic	20,890,580	18,252,681	19,666,131	18,252,092
Diluted loss per share attributable to common stock	$ (0.22)	$ (0.18)	$ (0.80)	$ (0.88)
Weighted average common shares outstanding, diluted	20,890,580	18,252,681	19,666,131	18,252,092
Comprehensive loss:				
Net loss	$ (4,700,248)	$ (3,235,485)	$ (15,651,274)	$ (16,005,040)
Net unrealized gain (loss) on available-for-sale securities	79	(5,824)	7,960	33,022
Comprehensive loss	$ (4,700,169)	$ (3,241,309)	$ (15,643,314)	$ (15,972,018)