Lipocine Announces Third Quarter 2020 Financial and Operational Results

SALT LAKE CITY, Nov. 10, 2020 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced financial results for the third quarter ended September 30, 2020 and provided a corporate update.

Third Quarter and Recent Corporate Highlights

- Completed patient enrollment in the LPCN 1144 Phase 2 *LiFT* ("**L**iver **F**at **i**ntervention with oral **T**estosterone") clinical study, a paired-biopsy study in confirmed pre-cirrhotic NASH subjects
    - Top-line results for change in liver fat data measured by MRI-PDFF (primary endpoint) expected in January 2021 and 36-week biopsy and MRI-PDFF data expected mid-2021
- Announced the peer-reviewed publication of LPCN 1144 Liver Fat Study results, "LPCN 1144 Resolves Non-Alcoholic Fatty Liver Disease in Hypogonadal Males" in Hepatology Communications
- Presented two abstracts at the 21st Annual Fall Scientific Meeting of the Sexual Medicine Society of North America ("SMSNA")
    - A study on the potential use of oral testosterone in COVID-19 highlighted key clinical evidence suggesting that low testosterone levels may play an important role on clinical outcomes
    - Results from a 24-day, open-label, single-arm, multicenter study confirming the validity of a fixed dose approach to orally administering TLANDO™ in hypogonadal men without the need for dose titration.

Ongoing Activities and Upcoming Milestones

- Presenting results from a preclinical study investigating LPCN 1144 treatment on hepatic fibrosis and non-alcoholic steatohepatitis ("NASH") features will be presented at The Liver Meeting Digital Experience™, hosted by the American Association for the Study of Liver Diseases ("AASLD") on November 13, 2020
- Announcing decision from U.S. Food and Drug Administration ("FDA") on the New Drug Application ("NDA") for TLANDO™

Third Quarter Ended September 30, 2020 Financial Results
Lipocine reported a net loss of $4.3 million, or ($0.07) per basic and diluted share, for the quarter ended September 30, 2020, compared with a net loss of $3.1 million, or ($0.12) per basic and diluted share, in the quarter ended September 30, 2019.

Research and development expenses were $2.5 million for the quarter ended September 30, 2020, compared with $1.7 million for the quarter ended September 30, 2019. The increase in research and development expenses during the three months ended September 30, 2020 was primarily due to a $280,000 increase in contract research organization and outside consulting and manufacturing costs related to the LPCN 1144 *LiFT* Phase 2 clinical study in NASH subjects, a $278,000 increase in commercial manufacturing costs related to TLANDO, a $160,000 increase in personnel expense, as well as increases in other R&D expenses of $56,000.

General and administrative expenses were $1.9 million for the quarter ended September 30, 2020, compared with $1.4 million for the quarter ended September 30, 2019. The increase in general and administrative expenses during the three months ended September 30, 2020 was primarily due to a $259,000 increase in legal costs, a $240,000 increase in personnel costs, and a $4,000 increase in other general and administrative expenses. These increases were offset by a $28,000 decrease marketing expense and a $17,000 decrease in administrative travel expenses.

As of September 30, 2020, we had $18.8 million of unrestricted cash, cash equivalents and marketable investment securities compared to $14.1 million at December 31, 2019. Additionally, as of September 30, 2020 and December 31, 2019 we had $5.0 million of restricted cash, which is required to be maintained as cash collateral under the SVB Loan and Security Agreement until TLANDO is approved by the FDA.

Nine Months Ended September 30, 2020 Financial Results
Lipocine reported a net loss of $16.5 million, or ($0.32) per basic and diluted share, for the nine months ended September 30, 2020, compared with a net loss of $9.7 million, or ($0.40) per basic and diluted share, for the nine months ended September 30, 2019.

Research and development expenses were $7.3 million for the nine months ended September 30, 2020, compared with $5.6 million for the nine months ended September 30, 2019. The increase in research and development expenses during the nine months ended September 30, 2020 was primarily due to a $2.9 million increase in contract research organization and outside consulting and manufacturing costs related to the LPCN 1144 *LiFT* Phase 2 clinical study in NASH subjects, a $430,000 increase in personnel expense, and a $50,000 increase in other research and development expenses. These increases were offset by a $1.7 million decrease in costs incurred in conjunction with TLANDO with the completion of the ABPM study in the first half of 2019, a $50,000 decrease in contract manufacturing costs for LPCN 1107, and a $46,000 decrease in costs for TLANDO XR.

General and administrative expenses were $5.9 million for the nine months ended September 30, 2020, compared with $4.0 million for the nine months ended September 30, 2019. The increase in general and administrative expenses during the nine months ended September 30, 2020 was primarily due to a $1.9 million increase in legal costs and a $228,000 increase in personnel costs. These increases were offset by a $77,000 decrease in administrative travel expense, a $68,000 decrease in marketing expense and a $43,000 decrease in other general and administrative expenses.

About Lipocine
Lipocine Inc. is a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders using its proprietary drug delivery technologies. Lipocine's clinical development pipeline includes: TLANDO, LPCN 1144, TLANDO XR, LPCN 1148 and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. Lipocine has resubmitted its NDA to the FDA for TLANDO. LPCN 1144, an oral product of bioidentical testosterone, recently completed a proof-of-concept clinical study demonstrating the potential utility in the treatment of non-cirrhotic NASH. LPCN 1144 is currently being studied in a Phase 2 clinical study. TLANDO XR, 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. In a phase 2 clinical evaluation when administered as once daily or twice daily TLANDO XR met the typical primary and secondary end points. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the treatment of cirrhosis. LPCN 1107 is potentially the first oral hydroxyprogesterone caproate product candidate, with end of phase 2 meeting completed, indicated for the prevention of recurrent preterm birth 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 regarding Lipocine's product candidates and related clinical trials, the FDA's review of our NDA related to TLANDO, the timing of completion of clinical trials, the timing and completion of regulatory reviews, outcomes of clinical trials of our product candidates, 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, new regulatory developments and requirements, risks related to the FDA approval process including 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 Balance Sheets
(Unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 12,938,186	$ 9,728,523
Restricted cash	5,000,000	5,000,000
Marketable investment securities	5,861,797	4,340,041
Accrued interest income	11,216	16,522
Prepaid and other current assets	915,575	545,887
Total current assets	24,726,774	19,630,973
Property and equipment, net of accumulated depreciation of $1,142,540 and $1,140,143, respectively	1,157	3,554
Other assets	23,753	23,753
Total assets	$ 24,751,684	$ 19,658,280
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,047,729	$ 1,182,241
Accrued expenses	1,534,495	449,303
Debt - current portion	3,206,290	3,333,333
Total current liabilities	5,788,514	4,964,877
Debt - non-current portion	3,151,010	3,814,407
Warrant liability	1,303,859	4,591,200
Total liabilities	10,243,383	13,370,484
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; 65,691,860 and 37,655,175 issued and 65,686,150 and 37,649,465 outstanding	6,569	3,766
Additional paid-in capital	182,062,701	157,391,969
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive gain (loss)	475	(38)
Accumulated deficit	(167,520,732)	(151,067,189)
Total stockholders' equity	14,508,301	6,287,796
Total liabilities and stockholders' equity	$ 24,751,684	$ 19,658,280

LIPOCINE INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
License revenue	$ -	$ 164,990	$ -	$ 164,990
Total revenues	-	164,990	-	164,990
Operating expenses:				
Research and development	$ 2,487,861	$ 1,713,417	$ 7,268,599	$ 5,627,383
General and administrative	1,887,195	1,427,261	5,925,991	3,989,645
Total operating expenses	4,375,056	3,140,678	13,194,590	9,617,028
Operating loss	(4,375,056)	(2,975,688)	(13,194,590)	(9,452,038)
Other income (expense):				
Interest and investment income	5,614	98,988	72,729	348,833
Interest expense	(84,293)	(183,500)	(305,485)	(611,864)
Gain (loss) on warrant liability	140,477	-	(3,025,997)	-
Total other expense, net	61,798	(84,512)	(3,258,753)	(263,031)
Loss before income tax expense	(4,313,258)	(3,060,200)	(16,453,343)	(9,715,069)
Income tax expense	-	-	(200)	(200)
Net loss	$ (4,313,258)	$ (3,060,200)	$ (16,453,543)	$ (9,715,269)
Basic loss per share attributable to common stock	$ (0.07)	$ (0.12)	$ (0.32)	$ (0.40)
Weighted average common shares outstanding, basic	64,833,714	24,911,908	52,030,431	24,301,045
Diluted loss per share attributable to common stock	$ (0.07)	$ (0.12)	$ (0.32)	$ (0.40)
Weighted average common shares outstanding, diluted	64,833,714	24,911,908	52,030,431	24,301,045
Comprehensive loss:				
Net loss	$ (4,313,258)	$ (3,060,200)	$ (16,453,543)	$ (9,715,269)
Net unrealized gain (loss) on available-for-sale securities	579	(2,656)	513	1,224
Comprehensive loss	$ (4,312,679)	$ (3,062,856)	$ (16,453,030)	$ (9,714,045)

SOURCE Lipocine Inc.

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https://ir.lipocine.com/2020-11-10-Lipocine-Announces-Third-Quarter-2020-Financial-and-Operational-Results