Lipocine Announces Financial Results for the Third Quarter Ended September 30, 2021

SALT LAKE CITY, Nov. 10, 2021 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced financial results for the third quarter and nine months ended September 30, 2021, and provided a corporate update.

Third Quarter and Recent Corporate Highlights

- Entered into a license agreement with Antares Pharma to commercialize TLANDO in the US
    - Lipocine to receive up to $21.0 million in licensing fees, including $11.0 million payable immediately and $10.0 million to be paid in the future subject to certain conditions
    - Lipocine is entitled to commercial sales milestone payments of up to $160.0 million and tiered royalties on net sales of TLANDO from mid-teens up to 20%
    - Antares Pharma to undertake all commercialization, post-marketing study obligations, and sourcing of TLANDO in the U.S.
    - Antares Pharma was also granted an option to license TLANDO XR for development and commercialization in the U.S. for additional licensing fees ($4.0 million), clinical and regulatory milestone payments ($35.0 million), sales milestone payments and royalties (mid-teens up to 20%)
- The U.S. Food and Drug Administration ("FDA") granted Fast Track Designation to LPCN 1144 for the treatment of non-cirrhotic non-alcoholic steatohepatitis ("NASH")
- The FDA has affirmed that the resubmission of the New Drug Application ("NDA") for TLANDO will be a Class 1 resubmission, with a two-month FDA review goal period
    - The FDA previously granted tentative approval to TLANDO in adult males indicated for conditions associated with a deficiency or absence of endogenous testosterone: primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired)
    - The product is not eligible for final approval and marketing in the U.S. until the expiration of the FDA's Orange Book listed exclusivity period previously granted to Clarus Therapeutics, Inc. with respect to Jatenzo®, which expires on March 27, 2022
- Announced positive topline 36-week results from its Phase 2 proof-of-concept **Li**ver **F**at intervention with oral **T**estosterone ("*LiFT")* clinical study, NCT04134091, investigating LPCN 1144 in men with biopsy-confirmed NASH
    - Study met its primary endpoint. At 12 weeks, treatment with LPCN 1144 resulted in statistically significant liver fat reduction, assessed by MRI-PDFF
    - Both LPCN 1144 treatment arms showed significant improvement in NASH without worsening of fibrosis
    - Efficacy and safety results from the *LiFT* study have been accepted for late-breaking presentations at the American Association for the Study of Liver Diseases ("AASLD") The Liver Meeting® on November 12-15, 2021
    - Company intends to meet with the FDA regarding the path forward for an accelerated approval and to discuss Phase 3 study requirements

Third Quarter Ended September 30, 2021 Financial Results

Lipocine reported a net loss of $3.1 million, or ($0.03) per diluted share, for the third quarter ended September 30, 2021, compared with a net loss of $4.3 million, or ($0.07) per diluted share, for the third quarter ended September 30, 2020.

Research and development expenses were $2.4 million for the third quarter ended September 30, 2021, compared with $2.5 million for the third quarter ended September 30, 2020. The decrease for the third quarter of 2021 was primarily due to a decrease in contract research organization expense and outside consulting costs related to our LPCN 1144 *LiFT* clinical study as well as decrease costs related to TLANDO. These decreases were offset by increases in costs associated with our LPCN 1154 and LPCN 1148 programs.

General and administrative expenses were $1.2 million for the third quarter ended September 30, 2021, compared with $1.9 million for the third quarter ended September 30, 2020. The decrease in general and administrative was primarily related to a decrease in our legal costs in 2021 as well as decreased personnel costs primarily related to reduced stock compensation expense.

As of September 30, 2021, the Company had $38.7 million of unrestricted cash, cash equivalents, and marketable investments, compared to $19.7 million of unrestricted cash, cash equivalents and marketable investment securities as of December 31, 2020.

Subsequent to the end of the third quarter, the Company received an $11.0 million upfront license fee as part of the licensing agreement with Antares Pharma to commercialize TLANDO.

Nine Months Ended September 30, 2021 Financial Results

Lipocine reported a net loss of $13.3 million, or ($0.15) per diluted share, for the nine months ended September 30, 2021, compared with a net loss of $16.5 million, or ($0.32) per diluted share, for the nine months ended September 30, 2020.

Research and development expenses were $5.4 million for the nine months ended September 30, 2021, compared with $7.3 million for the nine months ended September 30, 2020. The decrease in research and development expenses was primarily due to a decrease in contract research organization expense and outside consulting costs related to our LPCN 1144 *LiFT* clinical study, a decrease in costs related to TLANDO and a decrease in personnel costs primarily related to reduced stock compensation expense. These decreases were offset by increases in costs associated with our LPCN 1154 and LPCN 1148 programs.

General and administrative expenses were $4.3 million for the nine months ended September 30, 2021, compared with $5.9 million for the nine months ended September 30, 2020. The decrease in general and administrative expenses was primarily due to a decrease in our legal costs in 2021 as well as decreased personnel costs primarily related to reduced stock compensation expense. These decreases were offset by an increase in corporate insurance expense.

About Lipocine Inc.

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, LPCN 1154, and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, has received tentative approval from the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. LPCN 1144, an oral prodrug of bioidentical testosterone, recently completed a Phase 2 clinical study demonstrating the potential utility in the treatment of non-cirrhotic NASH. 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 1154 is an oral neuro-steroid targeted for the treatment of post-partum depression. 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. 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 the receipt of final FDA approval of TLANDO, the timing and amount of sales and development milestone payments and royalties under the License Agreement, the exercise of Antares' option with respect to TLANDO XR, the costs and timing of any post-marketing studies of TLANDO and clinical studies relating to TLANDO XR, our ability to compete in the TRT market, the degree to which TLANDO will gain market share in the TRT market, if at all, Antares Pharma's ability to successfully commercialize TLANDO, the benefits to Lipocine and Antares Pharma under the License Agreement, the potential benefits of TLANDO to patients, Lipocine's product candidates and related clinical trials, 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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 4,517,105	$ 19,217,382
Restricted cash	-	5,000,000
Marketable investment securities	34,145,380	449,992
Accrued interest income	159,230	391
Prepaid and other current assets	1,543,641	661,258
Total current assets	40,365,356	25,329,023
Other assets	23,753	23,753
Total assets	$ 40,389,109	$ 25,352,776
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 725,552	$ 1,597,220
Accrued expenses	1,571,012	1,653,178
Debt - current portion	3,135,979	3,333,333
Litigation settlement liability - current portion	1,000,000	-
Total current liabilities	6,432,543	6,583,731
Debt - non-current portion	-	2,257,075
Warrant liability	645,478	1,170,051
Litigation settlement liability - non-current portion	500,000	-
Total liabilities	7,578,021	10,010,857
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; 88,296,360 and 70,041,967 issued and 88,290,650 and 70,036,257 outstanding	8,830	7,005
Additional paid-in capital	218,136,818	187,407,634
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(3,420)	-
Accumulated deficit	(185,290,428)	(172,032,008)
Total stockholders' equity	32,811,088	15,341,919
Total liabilities and stockholders' equity	$ 40,389,109	$ 25,352,776

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
License revenue	$ 54,994	$ -	$ 54,994	$ -

Total revenues	54,994	-	54,994	-
Operating expenses:				
Research and development	$ 2,366,521	$ 2,487,861	$ 5,411,748	$ 7,268,599
General and administrative	1,222,146	1,887,195	4,281,690	5,925,991
Total operating expenses	3,588,667	4,375,056	9,693,438	13,194,590
Operating loss	(3,533,673)	(4,375,056)	(9,638,444)	(13,194,590)
Other income (expense):				
Interest and investment income	17,264	5,614	45,257	72,729
Interest expense	(44,839)	(84,293)	(171,241)	(305,485)
Unrealized gain (loss) on warrant liability	479,951	140,477	506,208	(3,025,997)
Litigation settlement	-	-	(4,000,000)	-
Total other income (expense), net	452,376	61,798	(3,619,776)	(3,258,753)
Loss before income tax expense	(3,081,297)	(4,313,258)	(13,258,220)	(16,453,343)
Income tax expense	-	-	(200)	(200)
Net loss	$ (3,081,297)	$ (4,313,258)	$ (13,258,420)	$ (16,453,543)
Basic loss per share attributable to common stock	$ (0.03)	$ (0.07)	$ (0.15)	$ (0.32)
Weighted average common shares outstanding, basic	88,290,650	64,833,714	86,477,640	52,030,431
Diluted loss per share attributable to common stock	$ (0.03)	$ (0.07)	$ (0.15)	$ (0.32)
Weighted average common shares outstanding, diluted	88,290,650	64,833,714	86,477,640	52,030,431
Comprehensive loss:				
Net loss	$ (3,081,297)	$ (4,313,258)	$ (13,258,420)	$ (16,453,543)
Net unrealized gain (loss) on available-for-sale securities	(3,234)	579	(3,420)	513
Comprehensive loss	$ (3,084,531)	$ (4,312,679)	$ (13,261,840)	$ (16,453,030)

SOURCE Lipocine Inc.

For further information: Morgan Brown, Executive Vice President & Chief Financial Officer, Phone: (801) 994-7383, mb@lipocine.com; Investors: Hans Vitzthum, Phone: (617) 535-7743, hans@lifesciadvisors.com

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