Lipocine Announces Financial Results For The Year Ended December 31, 2020

SALT LAKE CITY, March 11, 2021 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced financial results for the fourth quarter and year ended December 31, 2020, and provided a corporate update.

"Lipocine had a number of important accomplishments in 2020, most notably the U.S. Food and Drug Administration ("FDA") decision to grant tentative approval to TLANDO, the Company's oral testosterone product for testosterone replacement therapy ("TRT") in adult males with hypogonadism. We are committed to taking action to receiving final approval to permit the launch of the product," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. "We also made excellent progress advancing LPCN 1144 for the treatment of non-cirrhotic non-alcoholic steatohepatitis ("NASH"). We were pleased with the top-line results from our Phase 2 *LiFT* clinical study, announced in January 2021, which showed that treatment with LPCN 1144 resulted in significant liver fat reduction and improvement of key liver injury markers. The trial is on-going and we expect 36-week biopsy data in July/August 2021."

Fourth Quarter and Recent Corporate Highlights

- Granted tentative approval by the FDA for TLANDO, Lipocine's oral testosterone product for testosterone replacement therapy ("TRT") in adult males indicated for conditions associated with a deficiency or absence of endogenous testosterone
- Announced positive topline results from the Phase 2 *LiFT* ("Liver Fat intervention with oral Testosterone") clinical study, investigating LPCN 1144 in biopsy-confirmed NASH male subjects
    - Both LPCN 1144 treatment arms met the primary endpoint, change in hepatic fat fraction via magnetic resonance imaging proton density fat fraction ("MRI-PDFF"), with statistical significance
    - Statistically significant reduction in markers of liver injury were observed for LPCN 1144 compared to placebo
    - 36-week biopsy data from the LiFT study are expected in July/August 2021
- Began enrolling patients into an open label extension to the *LiFT* clinical study in which all patients will have access to LPCN 1144 (no placebo arm)
    - The extension will allow the collection of additional data on LPCN 1144 for up to a total of 72 weeks of therapy
- Raised gross proceeds in January 2021 of approximately $28.7 million in a public offering of approximately 16,428,571 million shares of common stock

Year Ended December 31, 2020 Financial Results
Lipocine reported a net loss of $21.0 million, or ($0.38) per diluted share, for the year ended December 31, 2020, compared with a net loss of $13.0 million, or ($0.50) per diluted share, for the year ended December 31, 2019.

Research and development expenses were $9.7 million for the year ended December 31, 2020, compared with $7.5 million for the year ended December 31, 2019. The increase in research and development expenses compared with the prior year was primarily due increases in contract research organization and outside consulting and manufacturing costs related to the LPCN 1144 LiFT Phase 2 clinical study, an increase in commercial manufacturing costs related to TLANDO, an increase in personnel expense, as well as a net increase in other R&D programs and expenses. Additionally, other costs related to TLANDO had a net decrease which was the result of a decrease in contract research organization expenses, offset by increases in other TLANDO expenses.

General and administrative expenses were $8.2 million for the year ended December 31, 2020, compared with $5.6 million for the year ended December 31, 2019. The increase in general and administrative expenses compared with the prior year was primarily due to an increase in legal costs, an increase in personnel costs, and an increase in other general and administrative expenses. These were offset by a decrease in administrative travel expenses and marketing expense.

As of December 31, 2020, Lipocine had $19.7 million of unrestricted cash, cash equivalents and marketable investment securities compared to $14.1 million as of December 31, 2019. Additionally, as of December 31, 2020 and December 31, 2019 Lipocine had $5.0 million of restricted cash, which was required to be maintained

as cash collateral under the Silicon Valley Bank ("SVB") Loan and Security Agreement until TLANDO is approved by the FDA. However, on February 16, 2021, Lipocine and SVB amended the Loan and Security Agreement to, among other things, remove the cash collateral requirement.

Subsequent to the end of the year, in January 2021, Lipocine raised gross proceeds of approximately $28.7 million in a public offering before deducting underwriting discounts and commissions and other offering expenses payable by Lipocine.

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 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 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 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 timing of completion of clinical trials and studies, the availability of additional data, 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 risk 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
Consolidated Balance Sheets
December 31, 2020 and 2019

	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 19,217,382	$ 9,728,523
Restricted cash	5,000,000	5,000,000
Marketable investment securities	449,992	4,340,041
Accrued interest income	391	16,522
Prepaid and other current assets	661,258	545,887
Total current assets	25,329,023	19,630,973
Property and equipment, net of accumulated depreciation of $1,143,697 and $1,140,143, respectively	-	3,554
Other assets	23,753	23,753
Total assets	$ 25,352,776	$ 19,658,280

Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,597,220	$ 1,182,241
Accrued expenses	1,653,178	449,303
Debt - current portion	3,333,333	3,333,333
Total current liabilities	6,583,731	4,964,877
Debt - non-current portion	2,257,075	3,814,407
Warrant liability	1,170,051	4,591,200
Total liabilities	10,010,857	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; 70,041,967 and 37,655,175 issued and 70,036,257 and 37,649,465 outstanding	7,005	3,766
Additional paid-in capital	187,407,634	157,391,969
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	-	(38)
Accumulated deficit	(172,032,008)	(151,067,189)
Total stockholders' equity	15,341,919	6,287,796
Total liabilities and stockholders' equity	$ 25,352,776	$ 19,658,280

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

Years Ended December 31, 2020 and 2019

	2020	2019
Revenues:		
License revenue	$ -	$ 164,990
Total revenues	-	164,990
Operating expenses:		
Research and development	9,748,469	7,468,210
General and administrative	8,247,795	5,597,070
Total operating expenses	17,996,264	13,065,280
Operating loss	(17,996,264)	(12,900,290)
Other income (expense)		
Interest and investment income	75,650	423,491
Interest expense	(386,618)	(766,745)
Gain on extinguishment of debt	234,802	-
Unrealized gain (loss) on warrant liability	(2,892,189)	236,400
Total other expense, net	(2,968,355)	(106,854)
Loss before income tax expense	(20,964,619)	(13,007,144)
Income tax expense	(200)	(200)

Net loss	$ (20,964,819)	$ (13,007,344)
Basic loss per share attributable to common stock	$ (0.38)	$ (0.50)
Weighted average common shares outstanding, basic	55,688,085	25,882,273
Diluted loss per share attributable to common stock	$ (0.38)	$ (0.50)
Weighted average common shares outstanding, diluted	55,688,085	25,882,273
Comprehensive loss:		
Net loss	$ (20,964,819)	$ (13,007,344)
Unrealized net gain on available-for-sale securities	38	925
Comprehensive loss	$ (20,964,781)	$ (13,006,419)

SOURCE Lipocine Inc.

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https://ir.lipocine.com/2021-03-11-Lipocine-Announces-Financial-Results-For-The-Year-Ended-December-31-2020