Lipocine Announces Financial and Operational Results for the Year Ended December 31, 2018

SALT LAKE CITY, March 6, 2019 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a specialty pharmaceutical company, today announced financial results for the year ended December 31, 2018.

Fourth Quarter 2019 and Recent Corporate Highlights

- Currently conducting an ABPM clinical study to assess TLANDO's effect on blood pressure, if any. The study has enrolled 138 subjects and results are currently expected before the end of the first quarter of 2019.
- The Patent Trial and Appeal Board ("PTAB") of the United States Patent and Trademark Office ("PTO") granted Lipocine's Priority Motion in the interference case with Clarus Therapeutics, and entered adverse judgment against Clarus. The PTAB ruling cancels all claims of the Clarus 8,828,428 patent. Clarus has filed an appeal of the PTAB judgement to the Court of Appeals for the Federal Circuit.
- Successfully completed a definitive phlebotomy study which supports the reliability of TLANDO clinical measurements conducted in the Phase 3 trials.
- Data from clinical trials of LPCN 1144 in potential non-alcoholic fatty liver disease ("NAFLD") patients were presented at the NASH-TAG Conference, January 2019, in Park City, UT.
- Data highlighting the association of hypogonadism and NAFLD and interim liver fat reductions with LPCN 1144 treatment were presented at the Keystone Symposia on Integrated Pathways of Disease in non-alcoholic steatohepatitis ("NASH") and NAFLD, January 2019 in Santa Fe, NM.
- Interim results from an ongoing sixteen-week Liver Fat Imaging study demonstrated meaningful liver fat reduction in patients treated with LPCN 1144. Liver fat changes were assessed using magnetic resonance imaging, proton density fat fraction ("MRI-PDFF") technique, a non-invasive quantitative biomarker of liver fat content.
    - Treatment results showed post-treatment absolute and relative mean reductions in liver fat of 7.6% and 38%, respectively, from baseline levels.
    - Sixteen-week results from the study are currently expected before the end of the first quarter of 2019.
- Received clearance by U.S. Food and Drug Administration ("FDA") for an Investigational New Drug ("IND") application to initiate a Phase 2 clinical study of LPCN 1144 in patients with biopsy confirmed NASH.

Year Ended December 31, 2018 Financial Results
Lipocine reported a net loss of $11.7 million, or ($0.55) per diluted share, for the year ended December 31, 2018, compared with a net loss of $21.0 million, or ($1.05) per diluted share, in the year ended December 31, 2017.

Research and development expenses were $6.5 million for the year ended December 31, 2018, compared with $11.0 million for the year ended December 31, 2017. The decrease in research and development expenses year over year was primarily due to reduced costs associated with TLANDO which include decreased contract research organization expenses, decreased contract manufacturing expenses and decreased outside services and consulting costs. Additionally, there were significant decreases in contract manufacturing expenses associated with LPCN 1107.

General and administrative expenses were $5.3 million for the year ended December 31, 2018, compared with $10.2 million for the year ended December 31, 2017. The decrease in general and administrative expenses year over year was primarily due to decreased personnel costs related to an overall reduction in headcount resulting in lower stock compensation expense, bonus expense, and salary and related benefit costs in 2018. Additionally, expenses for pre-commercialization marketing and sales activities related to TLANDO decreased significantly.

As of December 31, 2018, the Company had unrestricted cash, cash equivalents and marketable securities aggregating $15.3 million, compared to $21.4 million at December 31, 2017.

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 four development programs TLANDO, LPCN 1144, 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 received a Complete Response Letter from the FDA on May 8, 2018. LPCN 1144, an oral prodrug of bioidentical testosterone, is being developed as a treatment of non-

alcoholic steatohepatitis ("NASH") and is currently being studied in a proof-of-concept clinical study. 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 current and future clinical trials, the timing of completion and related expectations of clinical trials including the ongoing ABPM clinical trial with TLANDO and the Liver Fat Imaging study with LPCN 1144, the timing of resubmission of the NDA for TLANDO, 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, risks related to potential delays in filing and acceptance of our NDA for TLANDO, the risks that the FDA will not approve any of our products, including 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 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, 2018 and 2017

	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$ 8,077,539	$ 3,210,749
Restricted cash	5,000,000	-
Marketable investment securities	7,173,037	18,257,321
Accrued interest income	38,514	23,067
Litigation insurance recovery	-	3,319,927
Prepaid and other current assets	520,113	408,227
Total current assets	20,809,203	25,219,291
Property and equipment, net of accumulated depreciation of $1,124,700 and $1,121,080, respectively	18,997	75,070
Other assets	23,753	30,753
Total assets	$ 20,851,953	$ 25,325,114
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 671,280	$ 598,070
Litigation settlement payable	-	4,250,000
Accrued expenses	487,135	1,497,056
Debt - current portion	3,333,333	-
Total current liabilities	4,491,748	6,345,126
Debt - non-current portion	6,926,532	-
Total liabilities	11,418,280	6,345,126
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; 21,737,196 and 21,270,249 issued and 21,731,486 and 21,264,539 outstanding	2,174	2,127
Additional paid-in capital	147,533,019	145,423,012
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(963)	(4,616)
Accumulated deficit	(138,059,845)	(126,399,823)
Total stockholders' equity	9,433,673	18,979,988
Total liabilities and stockholders' equity	$ 20,851,953	$ 25,325,114

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

Years Ending December 31, 2018, 2017, and 2016

	2018	2017	2016
Revenues:			
License revenue	$ 428,031	$ -	$ -
Total revenues	428,031	-	-
Operating expenses:			
Research and development	6,464,708	11,004,281	8,076,053
General and administrative	5,289,142	10,213,695	10,382,146
Restructuring costs	-	-	728,635
Total operating expenses	11,753,850	21,217,976	19,186,834
Operating loss	(11,325,819)	(21,217,976)	(19,186,834)
Other income (expense), net	(333,503)	235,816	216,078
Loss before income tax expense	(11,659,322)	(20,982,160)	(18,970,756)
Income tax expense	(700)	(700)	(752)
Net loss	$ (11,660,022)	$ (20,982,860)	$ (18,971,508)
Basic loss per share attributable to common stock	$ (0.55)	$ (1.05)	$ (1.04)
Weighted average common shares outstanding, basic	21,352,339	20,051,934	18,258,149
Diluted loss per share attributable to common stock	$ (0.55)	$ (1.05)	$ (1.04)
Weighted average common shares outstanding, diluted	21,352,339	20,051,934	18,258,149
Comprehensive loss:			
Net loss	$ (11,660,022)	$ (20,982,860)	$ (18,971,508)
Unrealized net gain on available-for-sale securities	3,653	3,877	24,407
Comprehensive loss	$ (11,656,369)	$ (20,978,983)	$ (18,947,101)

SOURCE Lipocine Inc.

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

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