Lipocine Announces Financial Results for the Year Ended December 31, 2022

SALT LAKE CITY, March 10, 2023 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on treating Central Nervous System ("CNS") disorders by leveraging its proprietary platform to develop differentiated products, today announced financial results for the year ended December 31, 2022 and provided a corporate update.

In 2022, Lipocine announced a new strategic direction, focusing on the development of endogenous neuroactive steroids which have broad applicability in treating various CNS conditions. The Company is currently exploring partnering non-core assets including LPCN 1107, for prevention of pre-term birth, LPCN 1148, for the management of decompensated cirrhosis, LPCN 1144, for treatment of non-cirrhotic NASH, LPCN 1111, a once-a-day therapy candidate for TRT and LPCN 1021 (TLANDO in the U.S.) outside of the U.S.

Clinical Program Highlights
Neuroactive Steroids

- The Company completed an oral PK study and a food effect study with LPCN 1154 demonstrating the first enablement of effective oral delivery of brexanalone, a bioidentical neuroactive steroid.
- A pilot PK bridge study of LPCN 1154, an oral neuroactive steroid ("NAS") product candidate, in postpartum depression ("PPD") has been initiated. Results are expected in the first half of the year. The FDA has agreed with Lipocine's proposal for establishing the efficacy of LPCN 1154 via the 505(b)(2) pathway. The proof-of-concept study is a prelude to a pivotal study required for NDA filing.

LPCN 1148 in liver cirrhosis

- Enrollment has been completed in a Phase 2 proof-of-concept ("POC") study evaluating the therapeutic potential of LPCN 1148 for the management of decompensated cirrhosis of various etiologies. Topline results on the primary endpoint (change in skeletal muscle index at Week 24) are expected mid-2023.

TLANDO® for hypogonadism

- TLANDO™ was approved and granted Market Exclusivity by the U.S. Food and Drug Administration ("FDA") for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone (primary or hypogonadotropic hypogonadism). TLANDO™ has been licensed to Antares and was launched commercially in the U.S. in June 2022.

Year Ended December 31, 2022 Financial Results
Lipocine reported a net loss of $10.8 million, or ($0.13) per diluted share, for the year ended December 31, 2022, compared with a net loss of $634,399, or ($0.01) per diluted share, for the year ended December 31, 2021.

Lipocine recognized license revenue of $500,000 during the year ended December 31, 2022, compared to $16.1 million during the year ended December 31, 2021. License revenue in 2022 was related to a non-refundable cash fee of $500,000 received from Antares for consideration of a 90-day extension to exercise its option to license LPCN 1111. License revenue in 2021 primarily related to the Antares Licensing Agreement for TLANDO which was signed in October 2021 and was comprised of licensing fees, minimum royalties and the sale of finished goods inventory.

Research and development expenses were $8.6 million and $7.7 million, respectively, for the years ended December 31, 2022, and 2021. The increase in research and development expenses during the year ended December 31, 2022 was primarily due to an increase in contract research organization expense related to the Phase 2 POC study in male cirrhotic subjects with LPCN 1148, an increase in manufacturing scale up costs, an increase in personnel expense primarily resulting from additional headcount, and an increase in other R&D expenses. These increases were offset by decreases in costs related to LPCN 1144, LPCN 1107, and LPCN 1154.

General and administrative expenses were $4.1 million and $5.3 million, respectively, for the years ended December 31, 2022, and 2021. The decrease in general and administrative expenses during the year ended December 31, 2022 was primarily due to a decrease in legal fees, a decrease in personnel related costs and a decrease in other general and administrative expenses. These decreases were offset by an increase in costs related to the recruitment and compensation for two additional directors, an increase in other various professional fees, an increase in strategic advisory services, an increase related to proxy solicitation services, and an increase in travel related costs.

As of December 31, 2022, Lipocine had $32.5 million of unrestricted cash, cash equivalents and marketable investment securities compared to $46.6 million at December 31, 2021.

About Lipocine
Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery to develop products for CNS disorders. Lipocine has candidates in development as well as candidates for which we are exploring partnering. Our candidates represent enablement of patient friendly oral delivery options for favorable benefit to risk profile which target large addressable markets with significant unmet medical needs.

Lipocine clinical development candidates include: LPCN 1154, oral brexanolone, for the potential treatment of postpartum depression, LPCN 2101 for the potential treatment of epilepsy and LPCN 1148, an oral prodrug of bioidentical testosterone targeted for the management of symptoms associated with liver cirrhosis. Lipocine is exploring partnering opportunities for LPCN 1107, our candidate for prevention of pre-term birth, LPCN 1148, for the management of decompensated cirrhosis, LPCN 1144, our candidate for treatment of non-cirrhotic NASH, and LPCN 1111, a once-a-day therapy candidate for testosterone replacement therapy (TRT). TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate developed by Lipocine, is approved by the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. 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 our product development efforts, our strategic plans for developing products to treat CNS disorders, our ability to monetize non-core product candidates, including through entering into partnering arrangements, the application of our proprietary platform in developing new treatments for CNS disorders, our product candidates and related clinical trials, the achievement of milestones within and completion of clinical trials, the timing and completion of regulatory reviews, outcomes of clinical trials of our product candidates, and the potential uses and benefits of our product candidates. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that we may not be successful in developing product candidates to treat CNS disorders, we may not be able to enter into partnerships or other strategic relationships to monetize our non-core assets, 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, 2022 and 2021

	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 3,148,496	$ 2,950,552
Marketable investment securities	29,381,410	41,667,405
Accrued interest income	80,427	247,253
Contract asset - current	579,428	-
Prepaid and other current assets	945,319	1,514,465
Total current assets	34,135,080	46,379,675
Marketable investment securities	-	2,021,800
Contract asset - non-current	3,252,500	4,050,000
Property and equipment, net of accumulated depreciation of $1,153,530 and $1,144,077, respectively	131,589	7,211
Other assets	23,753	23,753
Total assets	$ 37,542,922	$ 52,482,439
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 600,388	$ 1,289,342
Accrued expenses	1,077,738	1,016,458

Debt - current portion	-	2,310,825
Litigation settlement liability - current portion	-	1,000,000
Total current liabilities	1,678,126	5,616,625
Warrant liability	229,856	795,796
Litigation settlement liability - non-current portion	-	500,000
Total liabilities	1,907,982	6,912,421
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, 200,000,000 and 100,000,000 shares authorized; 88,516,501 and 88,296,360 issued and 88,510,791 and 88,290,650 outstanding	8,852	8,830
Additional paid-in capital	219,112,164	218,286,323
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(20,321)	(18,016)
Accumulated deficit	(183,425,043)	(172,666,407)
Total stockholders' equity	35,634,940	45,570,018
Total liabilities and stockholders' equity	$ 37,542,922	$ 52,482,439

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

Years Ended December 31, 2022 and 2021

	2022	2021
Revenues	$ 500,000	$ 16,140,838
Operating expenses:		
Research and development	8,556,888	7,665,559
General and administrative	4,062,487	5,329,776
Total operating expenses	12,619,375	12,995,335
Operating income (loss)	(12,119,375)	3,145,503
Other income (expense)		
Interest and investment income	572,578	67,700
Interest expense	(27,098)	(203,292)
Unrealized gain on warrant liability	565,940	355,890
Gain (loss) on litigation settlement liability	250,000	(4,000,000)
Total other income (expense), net	1,361,420	(3,779,702)
Loss before income tax expense	(10,757,955)	(634,199)
Income tax expense	(681)	(200)
Net loss	$ (10,758,636)	$ (634,399)
Basic loss per share attributable to common stock	$ (0.12)	$ (0.01)
Weighted average common shares outstanding, basic	88,457,243	86,934,618
Diluted loss per share attributable to common stock	$ (0.13)	$ (0.01)
Weighted average common shares outstanding, diluted	88,875,946	87,623,452

Comprehensive loss:		
Net loss	$ (10,758,636)	$ (634,399)
Unrealized net loss on available-for-sale securities	(2,305)	(18,016)
Comprehensive loss	$ (10,760,941)	$ (652,415)

SOURCE Lipocine Inc.

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