Lipocine Announces Financial Results for the Full Year Ended December 31, 2023

SALT LAKE CITY, March 7, 2024 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on treating Central Nervous System ("CNS") disorders, today announced financial results for the year ended December 31, 2023 and provided a corporate update.

Neuroactive Steroids

- Lipocine announced positive topline results from a pharmacokinetics ("PK") pilot bridge study of LPCN 1154 (oral brexanolone). Lipocine is developing LPCN 1154 for postpartum depression ("PPD")
    - The bridge study results demonstrated comparative pharmacokinetics of LPCN 1154 to an approved IV infusion brexanolone
    - The study identified a dosing regimen of LPCN 1154 to be tested in a single confirmatory pivotal PK study required for NDA filing
    - LPCN 1154 treatment was well-tolerated with no hypoxia or sedation-related adverse events
- The Company completed a successful meeting with the U.S. Food and Drug Administration ("FDA") during which it confirmed with the FDA its proposal for a 505(b)(2) NDA filing based on a single pivotal study comparing exposure of LPCN 1154 with the approved IV infusion of brexanolone. The use of exposure parameters and criteria to assess comparable exposure to IV infusion brexanolone was also agreed upon
- In January 2024, Lipocine completed a single arm PK study (N=8) utilizing the "to be marketed" LPCN 1154 formulation and target dosing regimen. PK exposure results of the scaled-up formulation were consistent with the PK performance of the formulation evaluated in the pilot study. The study results confirm the 48-hour dosing regimen for the planned pivotal PK study
- The company anticipates beginning the LPCN 1154 pivotal study in Q1 '24. Top line results from the study are expected by the end of Q2 '24. Assuming the study meets expectations, the company plans to file an NDA at the end of Q4 '24
- Lipocine has identified a lead neuroactive steroid candidate for the management of essential tremor and is planning to submit a protocol for a proof-of-concept phase 2 study for Essential Tremor ("ET") in the first half of 2024

LPCN 1148

- Lipocine announced positive topline results from its Phase 2 proof-of-concept ("POC") study evaluating LPCN 1148 for the management of decompensated cirrhosis
    - The study met the primary endpoint: treatment with LPCN 1148 increased L3 skeletal muscle index (L3-SMI) relative to placebo ($P < 0.01$)
    - Fewer hepatic encephalopathy (HE) events of grade >1 were observed in the LPCN 1148 treatment arm relative to placebo ($P < 0.05$)
    - More patients on LPCN 1148 reported symptom improvement compared to those on placebo ($P < 0.05$)
    - LPCN 1148 was well-tolerated, with AE rates and severities similar to placebo
- Posters on LPCN 1148 and LPCN 1144 were presented at the European Association for the Study of the Liver (EASL) Congress 2023, in Vienna, Austria, June 21 – 24, 2023
- Updated results from the Phase 2 POC study were presented at The American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2023, in Boston, MA, November 2023
    - After week 24, all patients in the study entered into a single arm open-label extension ("OLE") stage and received LPCN 1148. Patients converting from placebo to LPCN 1148 in this OLE showed improvement in sarcopenia
- End of study results from the POC study are expected by the end of Q2 '24

TLANDO™

- In January 2024, Lipocine and Verity Pharma entered into an exclusive License Agreement under which Verity Pharma will market TLANDO in the United States and, if approved, in Canada
    - Verity Pharma is responsible for regulatory and marketing obligations in the U.S. and Canada, and for all further development of TLANDO and TLANDO XR
    - Verity Pharma agreed to pay Lipocine a license fee totaling $11 million. Upon execution of the agreement and upon transition of the commercialization of TLANDO to Verity, Lipocine received initial payments of $2.5 million and $5 million. Further payments of $2.5 million and $1 million are due from Verity Pharma no later than January 1, 2025,

and January 1, 2026, respectively
- Lipocine is entitled to receive up to $259 million in development and sales-based commercial milestone payments, as well as tiered royalty payments ranging from 12% up to 18% on net sales of TLANDO franchise products

Year Ended December 31, 2023 Financial Results

Lipocine reported a net loss of $16.4 million, or ($3.14) per diluted share, for the year ended December 31, 2023, compared with a net loss of $10.8 million, or ($2.15) per diluted share, for the year ended December 31, 2022.

During 2023 Lipocine recognized a non-cash minimum guaranteed royalties reversal of variable consideration revenue of$2.9 million related to the termination of the Antares License Agreement. The reversal of revenue is due to the fact that, as a result of the termination of the license agreement, the Company will not receive anticipated minimum royalties that were previously recorded for the Antares License Agreement. In 2022, the Company recorded revenue of $500,000 related to a non-refundable cash fee received from Antares.

Research and development expenses were $10.2 million and $8.6 million, respectively, for the years ended December 31, 2023 and 2022. The increase in research and development expenses was primarily due to an increase in contract research organization expense related to the LPCN 1154 clinical studies, an increase in TLANDO manufacturing related costs, an increase related to the LPCN 1148 Phase 2 POC study in male patients with cirrhosis, and an increase in personnel expense. These increases were offset by a decrease related to expenses incurred in 2022 for LPCN 1111 scale up costs, LPCN 1107 clinical study costs, and other research and development activities.

General and administrative expenses were $4.9 million and $4.1 million, respectively, for the years ended December 31, 2023 and 2022. The increase in general and administrative expenses was primarily due to an increase in business development and strategic advisory services expenses, an increase in legal fees, an increase in personnel related costs, an increase in franchise taxes, an increase in director fees, and an increase in other general and administrative expenses. These increases were offset by a decrease in corporate insurance expense, a decrease related to 2022 expenses for the recruitment of two additional directors, and a decrease in various consulting and professional fees.

As of December 31, 2023, Lipocine had $22.0 million of unrestricted cash, cash equivalents and marketable investment securities compared to $32.5 million at December 31, 2022.

Subsequent to year end, Lipocine received payments of$2.5 million and $5 million as part of the initial license fee from Verity Pharma in connection with the agreement entered into in January 2024 whereby Verity will take over commercialization of TLANDO, as described above.

About Lipocine

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

Lipocine's clinical development candidates include: LPCN 1154, oral brexanolone, for the potential treatment of postpartum depression, LPCN 2101 for the potential treatment of epilepsy, LPCN 2203 for the potential treatment of essential tremor and LPCN 1148, a novel androgen receptor agonist prodrug for oral administration targeted for the management of symptoms associated with liver cirrhosis. Lipocine is exploring partnering opportunities for LPCN 1107, our candidate for prevention of preterm birth, LPCN1154, for rapid relief of postpartum depression, LPCN 1148, for the management of decompensated cirrhosis, and LPCN 1144, our candidate for treatment of non-cirrhotic NASH. 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, the application of our proprietary platform in developing new treatments for CNS disorders, our lead neuroactive steroid candidate for the management of essential tremor, the timing of studies and clinical trials, our product candidates and related clinical trials, our development of and filing of a NDA with the FDA for LPCN 1154, the receipt of license fees, milestone payments and royalty payments under our license agreement with Verity Pharma, 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 have sufficient capital to complete the development processes for our product candidates, 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 and our ability to utilize a streamlined approval pathway for LPCN 1154, 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, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 4,771,758	$ 3,148,496
Marketable investment securities	17,263,788	29,381,410
Accrued interest income	52,254	80,427
Contract asset - current portion	-	579,428
Prepaid and other current assets	773,424	945,319
Total current assets	22,861,224	34,135,080
Contract asset - non-current portion	-	3,252,500
Property and equipment, net of accumulated depreciation of $1,182,191 and $1,153,530 respectively	116,095	131,589
Other assets	23,753	23,753
Total assets	$ 23,001,072	$ 37,542,922
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,395,977	$ 600,388
Accrued expenses	1,218,486	1,077,738
Warrant liability - current portion	17,166	-
Total current liabilities	2,631,629	1,678,126
Warrant liability	-	229,856
Total liabilities	2,631,629	1,907,982
Stockholders' equity:		
Common stock, par value $0.0001 per share, 200,000,000 shares authorized; 5,316,166 and 5,235,166 issued and 5,315,830 and 5,234,830 outstanding	8,860	8,852
Additional paid-in capital	220,171,250	219,112,164
Treasury stock at cost, 336 shares	(40,712)	(40,712)
Accumulated other comprehensive gain (loss)	7,259	(20,321)
Accumulated deficit	(199,777,214)	(183,425,043)
Total stockholders' equity	20,369,443	35,634,940
Total liabilities and stockholders' equity	$ 23,001,072	$ 37,542,922

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

	Years Ended December 31,	
	2023	**2022**
Revenues:		
License revenue	$ 109,987	$ 500,000
Minimum guaranteed royalties revenue (reversal of variable consideration)	(2,960,805)	-
Total revenues (reversal of variable consideration), net	(2,850,818)	500,000
Operating expenses:		
Research and development	10,175,251	8,556,888
General and administrative	4,904,888	4,062,487
Total operating expenses	15,080,139	12,619,375
Operating loss	(17,930,957)	(12,119,375)
Other income (expense):		
Interest and investment income	1,366,940	572,578
Interest expense	-	(27,098)
Unrealized gain on warrant liability	212,690	565,940
Gain on litigation settlement liability	-	250,000
Total other income, net	1,579,630	1,361,420
Loss before income tax expense	(16,351,327)	(10,757,955)
Income tax expense	(755)	(681)
Net loss	(16,352,082)	(10,758,636)
Issuance of Series B preferred stock dividend	(89)	-
Net loss attributable to common shareholders	$ (16,352,171)	$ (10,758,636)
Basic loss per share attributable to common stock	$ (3.10)	$ (2.06)
Weighted average common shares outstanding, basic	5,269,671	5,231,681
Diluted loss per share attributable to common stock	$ (3.14)	$ (2.15)
Weighted average common shares outstanding, diluted	5,269,671	5,256,169
Comprehensive loss:		
Net loss	$ (16,352,082)	$ (10,758,636)
Net unrealized gain (loss) on available-for-sale securities	27,580	(2,305)
Comprehensive loss	$ (16,324,502)	$ (10,760,941)

SOURCE Lipocine Inc.

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