Lipocine Announces Financial Results for the Full Year Ended December 31, 2024

SALT LAKE CITY, March 13, 2025 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery, today announced financial results for the year ended December 31, 2024, and provided a corporate update.

Oral Brexanolone

- LPCN 1154 is an oral formulation of the neuroactive steroid brexanolone that Lipocine is developing for the rapid treatment of postpartum depression (PPD).
- Lipocine held a meeting with the U.S. Food and Drug Administration (FDA) in the first quarter of 2025 to discuss the NDA submission package for LPCN 1154 (oral brexanolone) as a treatment for PPD. In the meeting, Lipocine was advised that the FDA believes that, in addition to the previously completed PK bridge data, a safety and efficacy study of oral LPCN 1154 in the target population will be required for 505(b)(2) NDA submission. Based on observed comparable exposure of LPCN 1154 and the reference drug in the PK bridge study, the company is initiating a phase 3 safety and efficacy study with expected first patient dosed in the second quarter of 2025
- The Company has completed registration stability studies required for NDA submission.
- A Phase 3 safety and efficacy study will provide the opportunity to generate safety and depression symptom relief data with LPCN 1154. Lipocine believes this data will be beneficial for potential inclusion in product labeling and for eligibility for clinical investigation exclusivity for a 48-hour, oral treatment option. In addition, the planned study will investigate the potential of oral brexanolone to treat anxiety disorders, representing another attractive commercial opportunity with a high unmet need.
- In October 2024, Lipocine announced positive data from a quantitative EEG (qEEG) study of oral brexanolone. The results indicate robust central nervous system (CNS) activity of oral brexanolone, with concentration- and time-dependent post-dose changes in qEEG. These results confirm $GABA_A$ positive allosteric modulation and support future development of oral brexanolone in neuropsychiatric indications.
- Lipocine is exploring the possibility of partnering LPCN 1154 with a third party.

LPCN 2401 for Obesity Management

- LPCN 2401 is targeted to be a once daily oral formulation comprising a proprietary anabolic androgen receptor agonist for obesity management. It is expected to have a favorable benefit to risk profile as an oral option for use as an adjunct to GLP-1 receptor agonist chronic weight management therapies and/or as a monotherapy post cessation ofGLP-1 receptor agonist therapies, with demonstrated benefits to the liver. Lipocine is exploring the possibility of partnering LPCN 2401 with a third party.
- LPCN 2401 was featured in a virtual key opinion leader (KOL) event hosted by Lipocine in October 2024
    - The event highlighted positive data from the Phase 2 study of LPCN 2401 which support the potential for the product to be used as an adjunct with incretin mimetics (GLP-1/GIP agonists) or as a monotherapy post incretin mimetic discontinuation.
- A poster "Oral LPCN 2401 Reduces Fat Mass and Increases Lean Mass in Men with Obesity" featuring the Phase 2 data was presented by Dr. Frank Greenway (Chief Medical Officer at Pennington Biomedical Research Center) at the Obesity Society's Annual Obesity Week conference in November 2024, in San Antonio, TX.

LPCN 1148

- LPCN 1148 is targeted to be a "First in Class" product candidate with a novel mechanism of action for the management of decompensated cirrhosis.
- A manuscript *"Oral LPCN 1148 Improves Sarcopenia and Hepatic Encephalopathy in Male Patients with Cirrhosis: a randomized, placebo-controlled Phase 2 trial"* was published in the journal Hepatology and also discussed at The Liver Meeting (AASLD) 2024 Editor's Cut: Clinical Study Session in November 2024.
    - The publication and conference discussion highlighted updated results from Lipocine's Phase 2 proof-of-concept clinical trial (LPCN 1148-21-001) that evaluated LPCN 1148 in men with decompensated cirrhosis and sarcopenia awaiting liver transplantation.
    - The results at 24 weeks showed that LPCN 1148 therapy resulted in a significant improvement in sarcopenia when compared with placebo.
    - Participants receiving LPCN 1148 also experienced significantly fewer episodes of overt hepatic encephalopathy (OHE) compared to those on placebo, even though most participants were already on background therapies for HE.

- The US FDA granted fast track designation to LPCN 1148 as a treatment for sarcopenia in patients with decompensated cirrhosis in December 2024. Lipocine is exploring the possibility of partnering LPCN 1148 with a third party.

TLANDO™

- Lipocine entered into an exclusive License Agreement with Verity Pharma in January 2024 under which Verity Pharma has the rights to market its oral testosterone replacement therapies TLANDO and, if approved, TLANDO XR, in the United States and Canada.
    - Under the terms of the License Agreement, Verity Pharma agreed to pay Lipocine license fees totaling $11 million. Of this amount, Lipocine received payments totaling $10 million during 2024 and is to receive a further payment of $1 million in 2025.
    - 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.
- In September 2024, we entered into a distribution and license agreement with SPC Korea Limited for the development and commercialization of TLANDO for TRT in South Korea. In October 2024, Lipocine signed an exclusive supply and distribution agreement with Pharmalink to commercialize TLANDO in the Gulf Cooperation Council (GCC) countries consisting of Saudi Arabia, Kuwait, the United Arab Emirates (UAE), Qatar, Bahrain, and Oman. The Company is exploring further partnerships for TLANDO outside of North America, South Korea and the GCC countries.

Testosterone

On February 28, 2025, the FDA informed sponsors of testosterone products about new labeling changes following the agency's review of the findings from the Testosterone Replacement Therapy for Assessment of Long-term Vascular Events and Efficacy Response in Hypogonadal Men (TRAVERSE) clinical trial and the results from required post-market ambulatory blood pressure (ABPM) studies. The changes include adding the TRAVERSE trial results to testosterone products, retaining "Limitation of Use" language for age-related hypogonadism, and removal of language from the Boxed Warning related to an increased risk of adverse cardiovascular outcomes for all testosterone products, in addition to other changes led by results of the ABPM studies.

Year Ended December 31, 2024 Financial Results

As of December 31, 2024, Lipocine had $21.6 million of unrestricted cash, cash equivalents and marketable investment securities compared to $22.0 million as of December 31, 2023.

Lipocine reported a net income of approximately $8,400 for the year ended December 31, 2024, compared with a net loss of $16.4 million, or ($3.14) per diluted share, for the year ended December 31, 2023.

The company recognized revenue of $11.2 million during the year ended December 31, 2024, compared to a net reversal of variable consideration revenue of $2.9 million during the year ended December 31, 2023. Revenue in 2024 primarily consisted of license revenue from the company's licensees, Verity Pharma, SPC Korea and Pharmalink and royalty revenue from TLANDO sales.

Research and development expenses were $7.4 million and $10.2 million, respectively, for the years ended December 31, 2024 and 2023. The decrease in research and development expenses in 2024 compared with the prior year was primarily due to completion of patient dosing expenses in the LPCN 1148 Phase 2 POC study in male patients with cirrhosis in 2023, a decrease in TLANDO related costs, and a decrease in personnel related costs. These decreases were offset by an increase in LPCN 1154 clinical studies, an increase in other lab supplies and research costs, and an increase in LPCN 2401 costs.

General and administrative expenses were $5.0 million and $4.9 million, respectively, for the years ended December 31, 2024 and 2023.

Interest and investment income was $1.2 million and $1.4 million, respectively, for the years ended December 31, 2024 and 2023.

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery to develop differentiated products. Lipocine has drug candidates in development as well as drug candidates for which we are exploring partnerships. 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 an oral candidate targeted for the management of essential tremor, LPCN 2401 an oral proprietary anabolic androgen receptor agonist, as an adjunct therapy to incretin mimetics, as an aid for improved body composition in obesity management 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, LPCN 1154, for rapid relief of postpartum depression, LPCN 2401 for obesity management, LPCN 1148, for the management of decompensated cirrhosis, and LPCN 1144, our candidate for treatment of metabolic dysfunction-associated steatohepatitis (MASH). 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 candidates and related clinical trials, our development of our product candidates and related efforts with the FDA, including with respect to LPCN 1154, our current intention to conduct a safety and efficacy study relating to LPCN 1154, the timing and potential results of the safety and efficacy study relating to LPCN 1154, potential partnering of our product candidates with third parties, 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, we may not have sufficient capital to complete the development processes for our product candidates or we may decide to allocate our available capital to other product candidates, we may not be able to enter into partnerships or other strategic relationships to monetize our non-core assets, safety and efficacy studies, including those relating to LPCN 1154, may not be successful or may not provide results that would support the submission of a NDA, the FDA may 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, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 6,205,926	$ 4,771,758
Marketable investment securities	15,427,385	17,263,788
Accrued interest income	120,447	52,254
Prepaid and other current assets	567,915	773,424
Total current assets	22,321,673	22,861,224
Property and equipment, net of accumulated depreciation of $1,223,297 and $1,182,191 respectively	165,075	116,095
Other assets	23,753	23,753
Total assets	$ 22,510,501	$ 23,001,072
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 271,696	$ 1,395,977
Accrued expenses	921,240	1,218,486
Deferred revenue	320,000	-
Warrant liability	-	17,166
Total current liabilities	1,512,936	2,631,629
Total liabilities	1,512,936	2,631,629

Stockholders' equity:		
Common stock, par value $0.0001 per share, 200,000,000 shares authorized; 5,348,276 and 5,316,166 issued and 5,347,940 and 5,315,830 outstanding, respectively	8,863	8,860
Additional paid-in capital	220,789,138	220,171,250
Treasury stock at cost, 336 shares	(40,712)	(40,712)
Accumulated other comprehensive gain	9,138	7,259
Accumulated deficit	(199,768,862)	(199,777,214)
Total stockholders' equity	20,997,565	20,369,443
Total liabilities and stockholders' equity	$ 22,510,501	$ 23,001,072

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Income (Loss)

	Years Ended December 31,	
	2024	**2023**
Revenues:		
License and royalty revenue	$ 11,198,144	$ 109,987
Minimum guaranteed royalties revenue (reversal of variable consideration)	-	(2,960,805)
Total revenues (reversal of variable consideration), net	11,198,144	(2,850,818)
Operating expenses:		
Research and development	7,351,753	10,175,251
General and administrative	5,001,426	4,904,888
Total operating expenses	12,353,179	15,080,139
Operating loss	(1,155,035)	(17,930,957)
Other income:		
Interest and investment income	1,146,902	1,366,940
Unrealized gain on warrant liability	17,166	212,690
Total other income	1,164,068	1,579,630
Income (loss) before income tax expense	9,033	(16,351,327)
Income tax expense	(681)	(755)
Net income (loss)	8,352	(16,352,082)
Issuance of Series B preferred stock dividend	-	(89)
Net gain (loss) attributable to common shareholders	$ 8,352	$ (16,352,171)
Basic income (loss) per share attributable to common stock	$ -	$ (3.10)
Weighted average common shares outstanding, basic	5,338,957	5,269,671
Diluted income (loss) per share attributable to common stock	$ -	$ (3.14)
Weighted average common shares outstanding, diluted	5,422,604	5,269,671
Comprehensive income (loss):		
Net income (loss)	$ 8,352	$ (16,352,082)

Net unrealized gain on available-for-sale securities	1,879	27,580
Comprehensive gain (loss)	$ 10,231	$ (16,324,502)

SOURCE Lipocine Inc.

For further information: Krista Fogarty, Phone: (801) 994-7383, kf@lipocine.com; Investors: PJ Kelleher, Phone: (617) 430-7579, pkelleher@lifesciadvisors.com

---