Lipocine Announces Financial Results for the First Quarter Ended March 31, 2025

SALT LAKE CITY, May 8, 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 first quarter ended March 31, 2025 and provided a corporate update.

Neuroactive Steroids

- Lipocine has initiated an outpatient Phase 3 safety and efficacy study of LPCN 1154, a non-invasive, rapid onset, oral formulation of brexanolone for the treatment of postpartum depression (PPD). Dosing of the first patient is anticipated in the second quarter of 2025. The Phase 3 study is expected to support a 505(b)(2) New Drug Application (NDA) submission in 2026.
- 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. It is expected to have a favorable benefit to risk profile as a non-invasive option for use as an adjunct to GLP-1 receptor agonist therapies and/or as a monotherapy post cessation of GLP-1 receptor agonist therapies with demonstrated benefits to the liver.
- Based on a pre-IND meeting and 2025 FDA draft guidance on Obesity and Overweight, the FDA recommends identifying the appropriate patient population for treatment, and also recommends that an approvable endpoint would be one that measures how a patient feels, functions, or survives. Therefore, in an upcoming proof-of-concept study of LPCN 2401 as an adjunct to GLP-1 agonist, Lipocine plans to target the elderly patient population, reportedly the population most vulnerable to lean mass and functionality loss while on GLP-1 agonist treatment, with plans to include functionality measures.
- Lipocine is exploring the possibility of partnering LPCN 2401 with a third party.

TLANDO®

- Lipocine has an exclusive License Agreement with Verity Pharma (Verity), entered into in 2024, under which Verity has the rights to market TLANDO, its oral testosterone replacement therapy, in the United States and Canada, if approved.
- In April 2025, Lipocine entered into a license and supply agreement with Aché granting exclusive rights to market TLANDO® in Brazil. Aché is a Brazilian pharmaceutical company founded nearly 60 years ago with a mission to improve people's lives. Today, Aché's products reach more than 20 countries across Latin America, Africa, Asia, and Europe, in addition to its home base in Brazil.
- Lipocine continues to explore partnering TLANDO in territories outside the U.S.,Canada, South Korea, the GCC countries and Brazil.

First Quarter Ended March 31, 2025, Financial Results

As of March 31, 2025, Lipocine had $19.7 million of unrestricted cash, cash equivalents and marketable investment securities compared to $21.6 million at December 31, 2024.

Lipocine reported a net loss of $1.9 million, or ($0.35) per diluted share, for the quarter ended March 31, 2025, compared with net income of $3.5 million, or $0.66 per diluted share, for the quarter ended March 31, 2024.

The company recognized royalty revenue from TLANDO sales of$94,000 during the quarter endedMarch 31, 2025, compared to royalty revenue of $117,000 during the quarter endedMarch 31, 2024. No license revenue was recognized during the quarter ended March 31, 2025, compared to$7.5 million in the quarter endedMarch 31, 2024. The license revenue in 2024 resulted from our license with Verity.

Research and development expenses were$1.1 million and $2.8 million, respectively, for the quarters endedMarch 31, 2025 and 2024. The decrease in research and development expenses was primarily a result of a decrease in costs related to our LPCN 1154 clinical studies in 2025 as compared to 2024, a decrease related to the wind down of our LPCN 1148 study in 2024, and a decrease in TLANDO related costs in 2025. These were offset by an increase in other research and development related costs and supplies in 2025.

General and administrative expenses were$1.1 million and $1.6 million, respectively, for the quarters endedMarch 31, 2025 and 2024. The decrease in general and administrative expenses primarily consisted of a decrease related to the one-time business development fees incurred in 2024 in conjunction with the Verity Pharmaceutical license agreement.

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to enable effective oral delivery of therapeutics. 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 P3 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
Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2025	December 31, 2024
Current assets:		
Cash and cash equivalents	$ 3,354,596	$ 6,205,926
Marketable investment securities	16,364,050	15,427,385
Accrued interest income	179,027	120,447
Prepaid and other current assets	428,795	567,915
Total current assets	20,326,468	22,321,673
Property and equipment, net of accumulated depreciation of $1,238,867 and $1,223,297 respectively	149,505	165,075
Other assets	23,753	23,753
Total assets	$ 20,499,726	$ 22,510,501

Current liabilities:		
Accounts payable	$ 360,239	$ 271,696
Accrued expenses	619,410	921,240
Deferred revenue	320,000	320,000
Total current liabilities	1,299,649	1,512,936
Total liabilities	1,299,649	1,512,936
Stockholders' equity:		
Common stock, par value $0.0001 per share, 200,000,000 shares authorized; 5,350,692 and 5,348,276 issued and 5,350,356 and 5,347,940 outstanding, respectively	8,863	8,863
Additional paid-in capital	220,860,140	220,789,138
Treasury stock at cost, 336 shares	(40,712)	(40,712)
Accumulated other comprehensive income	5,521	9,138
Accumulated deficit	(201,633,735)	(199,768,862)
Total stockholders' equity	19,200,077	20,997,565
Total liabilities and stockholders' equity	$ 20,499,726	$ 22,510,501

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(Unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Revenues:		
License revenue	$ -	$ 7,500,000
Royalty revenue	93,864	117,174
Total revenues	93,864	7,617,174
Operating expenses:		
Research and development	1,061,571	2,818,926
General and administrative	1,122,477	1,575,719
Total operating expenses	2,184,048	4,394,645
Operating income (loss)	(2,090,184)	3,222,529
Other income:		
Interest and investment income	225,511	331,364
Unrealized loss on warrant liability	-	(40,072)
Total other income	225,511	291,292
Income (loss) before income tax expense	(1,864,673)	3,513,821
Income tax expense	(200)	(200)
Net income (loss) attributable to common shareholders	$ (1,864,873)	$ 3,513,621
Basic earnings (loss) per share attributable to common stock	$ (0.35)	$ 0.66

Weighted average common shares outstanding, basic	5,348,557	5,315,830
Diluted earnings (loss) per share attributable to common stock	$ (0.35)	$ 0.66
Weighted average common shares outstanding, diluted	5,348,557	5,357,530
Comprehensive income (loss):		
Net income (loss)	$ (1,864,873)	$ 3,513,621
Net unrealized loss on marketable investment securities	(3,617)	(17,863)
Comprehensive income (loss)	$ (1,868,490)	$ 3,495,758

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

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