Lipocine Investor Room

Lipocine Announces Financial Results for the Full Year Ended December 31, 2025

SALT LAKE CITY, March 10, 2026 /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 full year ended December 31, 2025 and provided a corporate update.

"We believe 2025 was a pivotal year for Lipocine as we continue to advance our pipeline and expand our market presence. The progress we've made, especially with our postpartum depression therapeutic, LPCN 1154, demonstrates the strength of our science and our team's commitment to delivering more effective treatments for patients in need," said Dr Mahesh Patel, Lipocine President and CEO. "We're excited about the near-term milestones ahead and remain committed to advancing our pipeline proficiently."

Neuroactive Steroids (NAS)

LPCN 1154 for Postpartum Depression (PPD)

- Lipocine is developing LPCN 1154, a rapid onset, short treatment duration oral product candidate comprising the neuroactive steroid brexanolone for the treatment of postpartum depression.
- The last patient completed the final study visit (Last Patient/Last Visit) in a confirmatory Phase 3 safety and efficacy study evaluating LPCN 1154 as a treatment for PPD in February 2026. The study enrolled 90 patients in total and top line results are expected early in April 2026.
- If successful, the Phase 3 trial is expected to support a global registration package for LPCN 1154 in PPD, including a 505(b)(2) New Drug Application (NDA) submission in the U.S. which is expected in mid-2026.

LPCN 2201 for Major Depressive Disorders (MDD)

- Lipocine is advancing LPCN 2201, a unique oral brexanolone formulation, as a novel, rapid relief oral treatment option for MDD with the goal of improving outcomes without the limitations of existing therapies. LPCN 2201 is chemically identical to the endogenous human hormone allopregnanolone, a positive allosteric modulator of y-aminobutyric acid ($GABA_A$) receptor.

LPCN 2101 for Epilepsy

- Lipocine is developing LPCN 2101, a neuroactive steroid GABA positive allosteric modulator for epilepsy, including drug resistant epilepsy (DRE) and women with epilepsy (WWE), both of which pose significant treatment challenges under current standard of care.
- Two posters related to LPCN 2101 were presented at the2025 American Epilepsy Society (AES) Annual Meeting that took place in December 2025 in Atlanta, Georgia.
    - Oral Toxicokinetics of a Bioidentical $GABA_A$ Receptor Modulating Neuroactive Steroid (NAS) Anti-seizure Medication (ASM) Candidate for Women with Epilepsy (WWE)
    - Clinical Pharmacokinetics (PK) and Tolerability of a Novel Oral $GABA_A$ Receptor Positive Allosteric Modulating (PAM) Candidate for Epilepsy
- Based on FDA review of the protocol and agreement to proceed, the Company plans to initiate a Phase 2 proof-of-concept study to evaluate the safety, tolerability, and efficacy of LPCN 2101, subject to resource prioritization. Pre-clinical and Phase 1 studies have demonstrated promising PK results, safety and tolerability.

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 chronic weight management therapies and/or as a monotherapy post cessation of GLP-1 receptor agonist weight management therapies with demonstrated benefits to the liver.
- Pending further regulatory guidance, Lipocine may conduct a proof-of-concept Phase 2 study for LPCN 2401 in elderly obese and overweight GLP-1 eligible patients, with possible appropriate body composition and functional endpoints
- Lipocine may explore the possibility of partnering LPCN 2401 with a third party.

TLANDO™

- Lipocine has an exclusive License Agreement with Verity Pharma, entered into in 2024, under which Verity Pharma has the rights to market TLANDO, its oral testosterone replacement therapy, in the United States and Canada, if approved.

- Also in 2024, Lipocine entered into a distribution and license agreement with SPC Korea Limited for the development and commercialization of TLANDO for TRT in South Korea and Lipocine signed an exclusive supply and distribution agreement with Pharmalink to commercialize TLANDO in the Gulf Cooperation Council (GCC) countries. In 2025, Lipocine entered into a license and supply agreement with Aché in Brazil. The Company is exploring further partnerships for TLANDO outside of North America, South Korea, the GCC countries and Brazil.

Full year Ended December 31, 2025, Financial Results

As of December 31, 2025, Lipocine had $14.9 million of unrestricted cash, cash equivalents and marketable investment securities compared to $21.6 million as of December 31, 2024.

Lipocine reported a net loss of $9.6 million, or ($1.69) per diluted share, for the year ended December 31, 2025, compared with net income of $8,352, or ($0.00) per diluted share, for the year ended December 31, 2024.

Revenues were $2.0 million during the year ended December 31, 2025, compared to revenue of $11.2 million during the year ended December 31, 2024. Revenue in 2025 primarily consisted of license revenue from the Company's licenses with Verity and Aché of $1.5 million, and royalty revenue from TLANDO sales of $480,000. Revenue in 2024 primarily consisted of $10.9 million in license revenue from licenses with Verity, SPC and Pharmalink and royalty revenue from TLANDO sales of $298,000.

Research and development expenses were $8.6 million and $7.4 million, respectively, for the years ended December 31, 2025 and 2024. The increase in research and development expenses during the year ended December 31, 2025 primarily related to an increase in clinical study costs, in addition to other increases in supplies and research costs and in personnel-related costs.

General and administrative expenses were $3.8 million and $5.0 million, respectively, for the years ended December 31, 2025 and 2024. The decrease in general and administrative expenses during the year ended December 31, 2025 was primarily due to a decrease in business development, strategic advisory services and corporate legal fees, a decrease in estimated franchise taxes, a decrease in other various professional fees, and a decrease in corporate insurance expense, offset by an increase in personnel related expenses, an increase in patent related fees and an increase in other general and administrative expenses.

Interest and investment income was $0.7 million and $1.2 million for the years ended December 31, 2025 and 2024, respectively. The decrease in interest and investment income during the year ended December 31, 2025 was mainly due to declining cash and marketable investment securities balances in 2025 compared to 2024.

As of March 6, 2026, the Company had unrestricted cash, cash equivalents and marketable investment securities of approximately $24.7 million. The higher balance compared with the balance at December 31, 2025 was primarily a result of the sale of shares of common stock by means of an "At the Market ("ATM") Offering" under a sales agreement with A.G.P./Alliance Global Partners ("A.G.P") entered into in April 2024.

For further details on Lipocine's financial results from the year ended December 31, 2025, refer to Form 10K filed with the SEC.

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to develop innovative products with effective oral delivery. 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 development pipeline includes: LPCN 1154 for the treatment of postpartum depression, LPCN 2201 for treatment of major depressive disorder, LPCN 2101 for the treatment of epilepsy, LPCN 2203 targeted for the management of essential tremor, LPCN 2401 as an aid for improved body composition in obesity management, LPCN 1148 targeted for the management of symptoms associated with liver cirrhosis, and LPCN 1107 our candidate for prevention of preterm birth. 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, our Phase 3 safety and efficacy study relating to LPCN 1154, including the timing and potential results of the study, the timing of any submission of a NDA for LPCN 1154, 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 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, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 5,205,842	$ 6,205,926
Marketable investment securities	9,724,545	15,427,385
Accrued interest income	14,189	120,447
License fee and royalties receivable	1,145,390	91,405
Prepaid and other current assets	787,600	476,510
Total current assets	16,877,566	22,321,673
Property and equipment, net of accumulated depreciation of $1,284,079 and $1,223,297, respectively	104,293	165,075
Other assets	23,753	23,753
Total assets	$ 17,005,612	$ 22,510,501
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 971,822	$ 271,696
Accrued expenses	1,236,374	921,240
Deferred revenue	320,000	320,000
Total current liabilities	2,528,196	1,512,936
Total liabilities	2,528,196	1,512,936
Stockholders' equity:		
Common stock, par value $0.0001 per share, 75,000,000 shares authorized; 6,158,779 and 5,348,276 issued and 6,158,443 and 5,347,940 outstanding, respectively	8,944	8,863
Additional paid-in capital	223,901,106	220,789,138
Treasury stock at cost, 336 shares	(40,712)	(40,712)
Accumulated other comprehensive gain	4,445	9,138
Accumulated deficit	(209,396,367)	(199,768,862)
Total stockholders' equity	14,477,416	20,997,565
Total liabilities and stockholders' equity	$ 17,005,612	$ 22,510,501

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Income (Loss)

	Years Ended December 31,	
	2025	**2024**
Revenues:		
License revenue	$ 1,500,000	$ 10,900,000
Royalty revenue	476,677	298,144
Total revenues	1,976,677	11,198,144
Operating expenses:		
Research and development	8,583,919	7,351,753
General and administrative	3,764,137	5,001,426
Total operating expenses	12,348,056	12,353,179
Operating loss	(10,371,379)	(1,155,035)
Other income:		
Interest and investment income	744,074	1,146,902
Unrealized gain on warrant liability	-	17,166
Total other income	744,074	1,164,068
Income (loss) before income tax expense	(9,627,305)	9,033
Income tax expense	(200)	(681)
Net income (loss)	(9,627,505)	8,352
Basic income (loss) per share attributable to common stock	$ (1.77)	$ -
Weighted average common shares outstanding, basic	5,448,871	5,338,957
Diluted income (loss) per share attributable to common stock	$ (1.69)	$ -
Weighted average common shares outstanding, diluted	5,708,238	5,422,604
Comprehensive income (loss):		
Net income (loss)	$ (9,627,505)	$ 8,352
Net unrealized gain (loss) on available-for-sale securities	(4,693)	1,879
Comprehensive gain (loss)	$ (9,632,198)	$ 10,231

SOURCE Lipocine Inc.

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