

# Lipocine Announces Financial Results for the First Quarter Ended March 31, 2026

SALT LAKE CITY, May 7, 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 first quarter ended March 31, 2026 and provided a corporate update.

## **Neuroactive Steroids (NAS)**

### **LPCN 1154 for Postpartum Depression ("PPD")**

- In April 2026, Lipocine announced topline results from its Phase 3 placebo-controlled trial (N=90) evaluating LPCN 1154 (oral brexanolone) for the treatment of postpartum depression. LPCN 1154 did not show a statistically significant reduction from baseline in HAM-D (Hamilton Depression Rating Scale) total score compared to placebo at hour 60 in the full analysis set and the primary endpoint was not met.
- The Phase 3 results showed LPCN 1154 to be well tolerated, demonstrating a differentiated safety profile supportive of outpatient, at-home use, with no treatment-related serious adverse events, no cases of excessive sedation or loss of consciousness, and no treatment-related discontinuations.
- In a post hoc analysis of participants with a history of psychiatric conditions (n=54), LPCN 1154 showed statistically significant and clinically meaningful reductions in HAM-D scores versus placebo, observed as early as hour 12 and sustained through day 30.
- Based on these findings, Lipocine has applied for breakthrough therapy and fast track designations for LPCN 1154 in PPD and is awaiting FDA feedback.
- The Company intends to complete its full analysis of the Phase 3 trial data and plans to present results at upcoming medical conferences. For more information on the Phase 3 trial, refer to [clinicaltrials.gov: NCT06979544](https://clinicaltrials.gov/ct2/show/study/NCT06979544).
- The Company is evaluating all options regarding the potential path forward for LPCN 1154. Such options may include, but are not limited to, continued development of LPCN 1154, including the potential submission of a validation study protocol in patients with a history of psychiatric conditions, development of other product candidates, strategic transactions, partnerships, and other opportunities.

## **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.
- Lipocine has entered into additional license, supply and distribution agreements covering development and commercialization of TLANDO in other countries/ territories including Aché (Brazil), Pharmalink (GCC countries) and SPC (South Korea).
- 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, 2026, Financial Results**

As of March 31, 2026, Lipocine had \$24.7 million of unrestricted cash, cash equivalents and marketable investment securities compared to \$14.9 million at December 31, 2025.

Lipocine reported a net loss of \$3.7 million, or (\$0.52) per diluted share, for the quarter ended March 31, 2026, compared with a net loss of \$1.9 million, or (\$0.35) per diluted share, for the quarter ended March 31, 2025.

The company recognized royalty revenue from TLANDO sales of \$119,000 during the quarter ended March 31, 2026, compared to royalty revenue of \$94,000 during the quarter ended March 31, 2025.

Research and development expenses were \$2.8 million and \$1.1 million, respectively, for the quarters ended March 31, 2026 and 2025. The increase in research and development expenses was mainly the result of an increase in costs related to our LPCN 1154 clinical study in 2026.

General and administrative expenses were \$1.2 million and \$1.1 million, respectively, for the quarters ended March 31, 2026 and 2025. The increase in general and administrative expenses was primarily a result of an increase in various professional and consulting fees.

For further details on Lipocine's financial results for the quarter ended March 31, 2026, refer to Form 10-Q 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](http://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 the potential uses and benefits of products and product candidates, the commercial potential for product candidates, the timing of regulatory reviews and approvals and related procedures, and potential strategic opportunities. 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](http://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, 2026	December 31, 2025
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 5,015,608	\$ 5,205,842
Marketable investment securities	19,713,463	9,724,545
Accrued interest income	111,411	14,189
License fee and royalties receivable	119,397	1,145,390
Prepaid and other current assets	285,055	787,600
Total current assets	25,244,934	16,877,566
Property and equipment, net of accumulated depreciation of \$1,298,893 and \$1,284,079 respectively	89,479	104,293
Other assets	23,753	23,753
Total assets	\$ 25,358,166	\$ 17,005,612
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,562,728	\$ 971,822
Accrued expenses	645,115	1,236,374
Deferred revenue	320,000	320,000
Total current liabilities	2,527,843	2,528,196
Total liabilities	2,527,843	2,528,196

Stockholders' equity:

Common stock, par value \$0.0001 per share, 75,000,000

shares authorized; 7,475,451 and 6,158,779 issued and  
7,475,115 and 6,158,443 outstanding, respectively

	9,076	8,944
Additional paid-in capital	235,937,414	223,901,106
Treasury stock at cost, 336 shares	(40,712)	(40,712)
Accumulated other comprehensive income	(7,194)	4,445
Accumulated deficit	(213,068,261)	(209,396,367)
Total stockholders' equity	<u>22,830,323</u>	<u>14,477,416</u>
Total liabilities and stockholders' equity	<u>\$ 25,358,166</u>	<u>\$ 17,005,612</u>

**LIPOCINE INC. AND SUBSIDIARIES**

Condensed Consolidated Statements of Operations and Comprehensive Loss  
(Unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2026</b>	<b>2025</b>
Revenues:		
Royalty revenue	119,397	93,864
Total revenues	<u>119,397</u>	<u>93,864</u>
Operating expenses:		
Research and development	2,764,394	1,061,571
General and administrative	1,204,467	1,122,477
Total operating expenses	<u>3,968,861</u>	<u>2,184,048</u>
Operating loss	<u>(3,849,464)</u>	<u>(2,090,184)</u>
Other income:		
Interest and investment income	177,570	225,511
Total other income	<u>177,570</u>	<u>225,511</u>
Loss before income tax expense	<u>(3,671,894)</u>	<u>(1,864,673)</u>
Income tax expense	-	(200)
Net loss attributable to common shareholders	<u>\$ (3,671,894)</u>	<u>\$ (1,864,873)</u>
Basic loss per share attributable to common stock	<u>\$ (0.54)</u>	<u>\$ (0.35)</u>
Weighted average common shares outstanding, basic	<u>6,795,002</u>	<u>5,348,557</u>
Diluted loss per share attributable to common stock	<u>\$ (0.54)</u>	<u>\$ (0.35)</u>
Weighted average common shares outstanding, diluted	<u>6,795,002</u>	<u>5,348,557</u>
Comprehensive loss:		
Net loss	\$ (3,671,894)	\$ (1,864,873)
Net unrealized loss on marketable investment securities	(11,639)	(3,617)
Comprehensive loss	<u>\$ (3,683,533)</u>	<u>\$ (1,868,490)</u>

SOURCE Lipocine Inc.

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<https://ir.lipocine.com/2026-05-07-Lipocine-Announces-Financial-Results-for-the-First-Quarter-Ended-March-31,-2026>