Lipocine Investor Room

Lipocine Announces Financial Results for the Third Quarter Ended September 30, 2025

SALT LAKE CITY, Nov. 6, 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 third quarter ended September 30, 2025 and provided a corporate update.

Neuroactive Steroids (NAS)

LPCN 1154 for Postpartum Depression (PPD)

- LPCN 1154 (oral brexanolone) is a non-invasive, rapid onset, oral formulation of the neuroactive steroid brexanolone that Lipocine is developing for the treatment of PPD.
- A Phase 3 safety and efficacy study evaluating LPCN 1154 as a treatment for PPD continues to enroll patients and top-line data is expected in the second quarter of 2026. A meeting of the independent Data Safety Monitoring Board (DSMB) overseeing this trial will take place to review safety data from the first one-third of participants who were randomized and completed the day seven follow up visit, and the Company plans to provide a safety update in November 2025 following the DSMB review.
- Lipocine believes data from the Phase 3 study will be beneficial for potential inclusion in product labeling and for eligibility for clinical investigation exclusivity for a 48-hour, oral treatment option.
- 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 2026.
- On July 9, 2025, Lipocine hosted a virtual R&D investor event to discuss the current treatment landscape and unmet needs in PPD. The event featured presentations by Kristina M. Deligiannidis, MD (Zucker Hillside Hospital, Northwell Health, New York) and by company management. A replay of the webinar can be accessed here.
- Lipocine is exploring the possibility of partnering LPCN 1154 with a third party for commercialization.

LPCN 2101 for Epilepsy

- Lipocine is evaluating 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.
- The Company may 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.
- Two abstracts related to LPCN 2101 have been accepted for poster presentation at the 2025 American Epilepsy Society (AES) annual meeting to be held December 5-9 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

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 chronic 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 end points such as stair climb performance measure.
- 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. Rights to TLANDO have also been licensed to companies in South Korea, the GCC countries, and Brazil.

Third Quarter Ended September 30, 2025, Financial Results

As of September 30, 2025, Lipocine had $15.1 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 $3.2 million, or ($0.59) per diluted share, for the quarter ended September 30, 2025, compared with net loss of $2.2 million, or ($0.44) per diluted share, for the quarter ended September 30, 2024.

Royalty revenue from TLANDO sales was $115,000 during the quarter ended September 30, 2025. No royalty revenue was recorded during the comparable period in 2024.

Research and development expenses were $2.7 million and $1.6 million, respectively, for the quarters ended September 30, 2025 and 2024. The increase in research and development expenses was due to an increase in costs primarily related to the ongoing LPCN 1154 Phase 3 clinical trial in addition to other clinical trials, offset by a decrease in other research and development costs.

General and administrative expenses were $0.8 million and $1.1 million, respectively, for the quarters ended September 30, 2025 and 2024. The decrease in general and administrative expenses was primarily a result of a decrease in business development fees incurred in 2024, a decrease in Delaware franchise tax, and a decrease in other general and administrative costs, offset by an increase in legal fees.

Interest and investment income was $0.2 million and $0.3 million, respectively for the quarters ended September 30, 2025 and 2024. The decrease was due to lower interest rates and lower cash and marketable investment securities balances in 2025 as compared to 2024.

Nine Months Ended September 30, 2025, Financial Results

Lipocine reported a net loss of $7.3 million, or ($1.35) per diluted share, for the nine months ended September 30, 2025, compared with net loss of $1.8 million, or ($0.33) per diluted share, for the nine months ended September 30, 2024.

Lipocine recognized revenue of $831,000 and $7.7 million during the nine months ended September 30, 2025 and 2024, respectively. Revenue during the nine months ended September 30, 2025, consists of license revenue of $500,000 compared to license revenue of $7.5 million resulting from the Verity Licensing Agreement during the same period in 2024. During the nine months ended September 30, 2025, and 2024, the company recognized royalty revenue from TLANDO sales of $331,000 and $207,000, respectively.

Research and development expenses were $5.9 million and $6.3 million, respectively, for the nine month periods ended September 30 2025 and 2024. The decrease was a result of lower costs related to the LPCN 1154 Phase 3 clinical study in 2025 as compared to LPCN 1154 studies which occurred in 2024, and a decrease in other research and development related costs and supplies in 2025, offset by an increase in costs related to the initiation of the LPCN 2401 clinical study.

General and administrative expenses were $2.8 million and $4.1 million, respectively, for the nine-month period ended September 30 2025 and 2024. The decrease was a result of a decrease in business development fees, a decrease related to fees incurred in 2024 in conjunction with the Verity Pharmaceutical license agreement, a decrease in other general and administrative costs, a decrease in legal fees and a decrease in estimated Delaware franchises taxes.

Interest and investment income was $0.6 million and $0.9 million, respectively, for the nine months ended September 30 2025, and 2024. The decrease was due to lower interest rates and lower cash and marketable investment securities balances in 2025 as compared to 2024.

For further details on Lipocine's financial results from the three and nine months ended September 30, 2025, refer to Form 10Q 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 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, LPCN 2101, and LPCN 2401, our Phase 3 safety and efficacy study relating to LPCN 1154, the timing and potential results of the safety and efficacy study relating to LPCN 1154, the potential Phase 2 proof-of-concept studies for LPCN 2101 and LPCN 2401, 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 assets, clinical and other 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 and our other product candidates, 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)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 3,901,040	$ 6,205,926
Marketable investment securities	11,230,031	15,427,385
Accrued interest income	115,272	120,447
Prepaid and other current assets	683,797	567,915
Total current assets	15,930,140	22,321,673
Property and equipment, net of accumulated depreciation of $1,269,098 and $1,223,297 respectively	119,274	165,075
Other assets	23,753	23,753

Total assets	$ 16,073,167	$ 22,510,501
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 861,452	$ 271,696
Accrued expenses	749,667	921,240
Deferred revenue	320,000	320,000
Total current liabilities	1,931,119	1,512,936
Total liabilities	1,931,119	1,512,936
Stockholders' equity:		
Common stock, par value $0.0001 per share, 75,000,000 shares authorized; 5,420,592 and 5,348,276 issued and 5,420,256 and 5,347,940 outstanding, respectively	8,870	8,863
Additional paid-in capital	221,195,546	220,789,138
Treasury stock at cost, 336 shares	(40,712)	(40,712)
Accumulated other comprehensive income	4,627	9,138
Accumulated deficit	(207,026,283)	(199,768,862)
Total stockholders' equity	14,142,048	20,997,565
Total liabilities and stockholders' equity	$ 16,073,167	$ 22,510,501

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenues:				
License revenue	$ -	$ -	$ 500,000	$ 7,500,000
Royalty revenue	114,574	-	331,287	206,738
Total revenues	114,574	-	831,287	7,706,738
Operating expenses:				
Research and development	2,707,777	1,585,233	5,906,118	6,278,881
General and administrative	767,837	1,045,240	2,780,747	4,128,371
Total operating expenses	3,475,614	2,630,473	8,686,865	10,407,252
Operating loss	(3,361,040)	(2,630,473)	(7,855,578)	(2,700,514)
Other income:				
Interest and investment income	174,208	273,574	598,357	913,784
Unrealized gain on warrant liability	-	138,081	-	13,580
Total other income	174,208	411,655	598,357	927,364
Loss before income tax expense	(3,186,832)	(2,218,818)	(7,257,221)	(1,773,150)
Income tax expense	-	-	(200)	(681)
Net loss attributable to common shareholders	$ (3,186,832)	$ (2,218,818)	$ (7,257,421)	$ (1,773,831)
Basic loss per share attributable to common stock	$ (0.59)	$ (0.41)	$ (1.35)	$ (0.33)
Weighted average common shares outstanding, basic	5,413,149	5,347,940	5,371,458	5,335,941
Diluted loss per share attributable to common stock	$ (0.59)	$ (0.44)	$ (1.35)	$ (0.33)

Weighted average common shares outstanding, diluted	5,413,149	5,347,940	5,371,458	5,335,941
Comprehensive income (loss):				
Net loss	$ (3,186,832)	$ (2,218,818)	$ (7,257,421)	$ (1,773,831)
Net unrealized income (loss) on marketable investment securities	5,870	19,661	(4,511)	2,683
Comprehensive loss	$ (3,180,962)	$ (2,199,157)	$ (7,261,932)	$ (1,771,148)

SOURCE Lipocine Inc.

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