Lipocine Investor Room

# Lipocine Announces Financial Results for the Second Quarter Ended June 30, 2025

SALT LAKE CITY, Aug. 5, 2025 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company leveraging its proprietary technology platform to develop innovative products with effective oral delivery, today announced financial results for the second quarter ended June 30, 2025 and provided a corporate update.

Neuroactive Steroids

- LPCN 1154 (oral brexanolone product candidate) is a non-invasive, 48-hour treatment option targeted for rapid symptom relief of postpartum depression (PPD), a serious unmet medical need. LPCN 1154 could have advantages with respect to limitations on daily activities, treatment duration, and time to effect.
- During the second quarter, Lipocine began treating patients with PPD in the pivotal Phase 3 safety and efficacy study of LPCN 1154. This outpatient trial is expected to support a global registration package for LPCN 1154 in PPD, with topline results expected in the second quarter of 2026 and a 505(b)(2) New Drug Application (NDA) submission in the U.S. expected in mid-2026.
- On July 9, 2025, Lipocine hosted a virtual R&D investor event featuring a presentation by Kristina M. Deligiannidis, MD (Zucker Hillside Hospital, Northwell Health, New York) discussing the current treatment landscape and unmet needs in PPD, followed by a company management presentation which reviewed the target attributes of LPCN 1154, provided a clinical development progress update including relevant data and rationale for success, and discussed next steps in the product development. A replay of the webinar can be accessed here.
- Lipocine may explore the possibility of partnering LPCN 1154 with a third party for commercialization.

LPCN 2401 for Management of GLP-1 Agonist Use in Obesity

- LPCN 2401 is targeted to be a once daily oral formulation comprising a proprietary anabolic androgen receptor agonist, a regulator of myostatin. It is expected to have a favorable benefit to risk profile as a non-invasive option as an adjunct to GLP-1 receptor agonist use for quality weight loss though improved body composition and/or as a monotherapy for weight maintenance and/or newly achieved glycemic status post cessation of GLP-1 receptor agonist use with demonstrated liver benefits.
- Lipocine plans to initiate a proof-of-concept Phase 2 study for LPCN 2401 in obese and overweight GLP-1 eligible patients, with appropriate body composition and functional endpoints such as measured by stair climb performance with first patient dosing targeted for the third quarter of 2025.
- 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. In addition to the Verity License Agreement, Lipocine has entered into license/distribution agreements with SPC Korea for South Korea and Pharmalink for the GCC countries.
- In June 2025, Verity Pharma filed a New Drug Submission (NDS) for TLANDO® in Canada.
- In April 2025, Lipocine entered a license and supply agreement with Aché Laboratórios Farmacêuitcos S.A., granting an exclusive license to commercialize TLANDO in Brazil. Under the agreement, Lipocine is entitled to receive fees upon the achievement of certain regulatory milestones, royalties on net sales and will supply TLANDO to Aché at an agreed transfer price. TLANDO is expected to be the first oral testosterone product to be registered in Brazil.

**Second Quarter Ended June 30, 2025, Financial Results**

As of June 30, 2025, Lipocine had $17.9 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 $2.2 million, or ($0.41) per diluted share, for the quarter ended June 30, 2025, compared with net loss of $3.1 million, or $0.57) per diluted share, for the quarter ended June 30, 2024.

The company recognized royalty revenue from TLANDO sales of $123,000 during the three months ended June 30, 2025, compared to royalty revenue of $90,000 during the three months ended June 30, 2024. In addition, License revenue of $500,000 was recognized in the three months ended June 30, 2025. There was no license revenue in the comparable period of 2024.

Research and development expenses were $2.1 million and $1.9 million, respectively, for the quarters ended June 30, 2025 and 2024. The increase in research and development expenses was due to an increase in costs related to the initiation of our LPCN 2401 clinical studies, and an increase in other research and development costs.

General and administrative expenses were $0.9 million and $1.5 million, respectively, for the quarters ended June 30, 2025 and 2024. The decrease in general and administrative expenses during was primarily a result of a decrease in business development fees and consulting expenses compared to what was incurred in 2024, a decrease in legal fees, a decrease in Delaware franchise tax as a result of the reduction in authorized common stock from 200,000,000 down to 75,000,000 shares, a decrease in other professional fees and general and administrative related costs, and a decrease in corporate insurance premiums.

**Six Months Ended June 30, 2025, Financial Results**

Lipocine reported a net loss of $4.1 million, or ($0.76) per diluted share, for the six months ended June 30, 2025, compared with net income of $0.4 million, or ($0.10) per diluted share, for the six months ended June 30, 2024.

Lipocine recognized revenue of $717,000 and $7.7 million during the six months ended June 30, 2025 and 2024, respectively. Revenue during the six months ended June 30, 2025, consisted 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 six months ended June 30, 2025, and 2024, the company recognized royalty revenue from TLANDO sales of $217,000 and $207,000, respectively.

Research and development expenses were $3.2 million and $4.7 million, respectively, for the six month periods ended June 30, 2025 and 2024. The decrease was a result of lower costs related to the initiation of the LPCN 1154 Phase 3 clinical study in 2025 as compared to LPCN 1154 studies which occurred in 2024 in addition to a decrease in other research and development related costs and supplies in 2025, offset by an increase in costs related to the initiation of our LPCN 2401 clinical studies and an increase in personnel related costs.

General and administrative expenses were $2.0 million and $3.1 million, respectively, for the six month periods ended June 30, 2025 and 2024. The decrease was a result of the one-time business development fees incurred in 2024 in conjunction with the Verity Pharmaceutical license agreement, as well as decreases in other business development expenses, legal fees, corporate insurance premiums, professional fees and other general and administrative costs.

Interest and investment income was $0.4 million and $0.6 million, respectively, for the six months ended June 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 six months ended June 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 PPD, LPCN 2101 for the potential treatment of refractory 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 PPD, 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 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, 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)

| | June 30, 2025 | December 31, 2024 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 6,043,980 | $ 6,205,926 |
| Marketable investment securities | 11,891,702 | 15,427,385 |
| Accrued interest income | 121,732 | 120,447 |
| Prepaid and other current assets | 362,629 | 567,915 |
| Total current assets | 18,420,043 | 22,321,673 |
| Property and equipment, net of accumulated depreciation of $1,254,975 and $1,223,297 respectively | 133,397 | 165,075 |
| Other assets | 23,753 | 23,753 |
| Total assets | $ 18,577,193 | $ 22,510,501 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 442,994 | $ 271,696 |
| Accrued expenses | 685,779 | 921,240 |
| Deferred revenue | 320,000 | 320,000 |
| Total current liabilities | 1,448,773 | 1,512,936 |
| Total liabilities | 1,448,773 | 1,512,936 |
| Stockholders' equity: | | |
| Common stock, par value $0.0001 per share, 75,000,000 shares authorized; 5,374,431 and 5,348,276 issued and 5,374,095 and 5,347,940 outstanding, respectively | 8,865 | 8,863 |
| Additional paid-in capital | 221,000,961 | 220,789,138 |
| Treasury stock at cost, 336 shares | (40,712) | (40,712) |
| Accumulated other comprehensive income | (1,243) | 9,138 |
| Accumulated deficit | (203,839,451) | (199,768,862) |
| Total stockholders' equity | 17,128,420 | 20,997,565 |

| | | |
|---|---|---|
| Total liabilities and stockholders' equity | $ 18,577,193 | $ 22,510,501 |

**LIPOCINE INC. AND SUBSIDIARIES**

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(Unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Revenues: | | | | |
| License revenue | $ 500,000 | $ - | $ 500,000 | $ 7,500,000 |
| Royalty revenue | 122,849 | 89,565 | 216,713 | 206,738 |
| Total revenues | 622,849 | 89,565 | 716,713 | 7,706,738 |
| Operating expenses: | | | | |
| Research and development | 2,136,769 | 1,874,721 | 3,198,341 | 4,693,646 |
| General and administrative | 890,433 | 1,507,412 | 2,012,910 | 3,083,131 |
| Total operating expenses | 3,027,202 | 3,382,133 | 5,211,251 | 7,776,777 |
| Operating loss | (2,404,353) | (3,292,568) | (4,494,538) | (70,039) |
| Other income (loss): | | | | |
| Interest and investment income | 198,637 | 308,845 | 424,149 | 640,209 |
| Unrealized loss on warrant liability | - | (84,430) | - | (124,502) |
| Total other income | 198,637 | 224,415 | 424,149 | 515,707 |
| Income (loss) before income tax expense | (2,205,716) | (3,068,153) | (4,070,389) | 445,668 |
| Income tax expense | - | (481) | (200) | (681) |
| Net income (loss) attributable to common shareholders | $ (2,205,716) | $ (3,068,634) | $ (4,070,589) | $ 444,987 |
| Basic earnings (loss) per share attributable to common stock | $ (0.41) | $ (0.57) | $ (0.76) | $ 0.08 |
| Weighted average common shares outstanding, basic | 5,351,957 | 5,343,922 | 5,350,267 | 5,329,876 |
| Diluted earnings (loss) per share attributable to common stock | $ (0.41) | $ (0.56) | $ (0.76) | $ 0.10 |
| Weighted average common shares outstanding, diluted | 5,351,957 | 5,343,922 | 5,350,267 | 5,459,204 |
| Comprehensive income (loss): | | | | |
| Net income (loss) | $ (2,205,716) | $ (3,068,634) | $ (4,070,589) | $ 444,987 |
| Net unrealized income (loss) on marketable investment securities | (6,764) | 885 | (10,381) | (16,978) |
| Comprehensive income (loss) | $ (2,212,480) | $ (3,067,749) | $ (4,080,970) | $ 428,009 |

SOURCE Lipocine Inc.

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