# Lipocine Announces Financial Results for the First Quarter Ended March 31, 2024

SALT LAKE CITY, May 9, 2024 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company, today announced financial results for the first quarter ended March 31, 2024 and provided a corporate update.

LPCN 1154 for Postpartum Depression

- In May 2024, dosing of subjects was completed in the pivotal pharmacokinetic (PK) study designed to support a New Drug Application (NDA) for LPCN 1154. LPCN 1154, oral brexanolone, is being developed as a treatment for postpartum depression
- The FDA has agreed with Lipocine's proposal for establishing the efficacy of LPCN 1154 through the pivotal PK bridge to an approved IV infusion of brexanolone via a 505(b)(2) NDA filing
- Topline results from the pivotal PK study are expected late in 2Q 2024. Positive results would support an NDA filing at the end of Q4 2024

LPCN 1148 for Management of Cirrhosis

- In March 2024, Lipocine announced positive Week 52 results from the LPCN 1148 Phase 2 study in patients with cirrhosis. The study met primary and hepatic encephalopathy endpoints
    - Increase in Skeletal Muscle Index (SMI) observed at Week 24 was maintained through 52 weeks
    - Participants on placebo increased SMI when switched to LPCN 1148
- Patients on LPCN 1148 therapy had fewer overt hepatic encephalopathy (OHE) events and longer time to first recurrent OHE event, with no OHE background therapy restrictions
- LPCN 1148 was well-tolerated, with adverse events (AE) rates and severities similar to placebo. Participants on LPCN 1148 were hospitalized for fewer days

LPCN 2401 for Obesity Management

- In April 2024, Lipocine announced positive clinical results from a multi-center prospective, blinded Phase 2 study evaluating LPCN 2401 in participants with obesity (BMI ≥30) and participants with BMI ≥27 with at least one weight-related comorbidity
- Results showed treatment with LPCN 2401 resulted in statistically significant body composition improvements
    - Increased lean mass (LM) by 4.4% and decreased fat mass (FM) by 6.7%
    - Reduced android fat (AF) by 4.1% and increased bone mineral content (BMC) by 2.8%
- LPCN 2401 was well-tolerated; AEs were similar to placebo. A replay of the webcast discussing the LPCN 2401 Phase 2 results can be accessed on Lipocine's website here
- Potential for LPCN 2401 to be used in combination with incretin mimetics (GLP-1 agonists and GLP/GIP dual agonists) for improved body composition (ameliorate muscle loss with android fat loss) or as a monotherapy post discontinuation

LPCN 2203 for Essential Tremor

- Oral GABA Positive Allosteric Modulator, targeting improved efficacy with fewer side effects e.g. somnolence, dizziness
- Daytime efficacy and improved tolerability remains an unmet need
- Achieved relevant target blood levels with good tolerability in multiple Phase 1 studies with no incidence of somnolence, sedation or dizziness

TRT Franchise - TLANDO™ and LPCN 1111 (TLANDO XR)

- In January 2024, Lipocine and Verity Pharma entered into an exclusive License Agreement under which Verity Pharma will market TLANDO in the United States and, if approved, in Canada. The terms of the license agreement call for a license fee of $11 million and development and sales milestones of up to $259 million in aggregate, dependent on achievement of certain milestones. In addition, the Company is eligible to receive tiered royalty payments ranging from 12% up to 18% on net sales in the U.S. and Canada.

**First Quarter Ended March 31, 2024 Financial Results**

Lipocine reported net income of $3.5 million, or $0.66 per diluted share, for the first quarter ended March 31, 2024, compared with a net loss of $3.9 million, or ($0.76) per diluted share, for the quarter ended March 31, 2023.

Revenue in the first quarter of 2024 was $7.6 million, primarily consisting of licensing revenue received from the Verity License Agreement. This compares with revenue of $0.06 million in the comparable period in 2023.

Research and development expenses were $2.8 million and $3.1 million, respectively, for the quarters ended March 31, 2024 and 2023. The decrease in research and development expenses was a result of a decrease in contract research organization expense and outside consulting costs related to the completion of our LPCN 1148 study late in 2023, a decrease in personnel related costs, and a

decrease in LPCN 1111 costs, offset by an increase in costs related to our LPCN 1154 clinical studies, and an increase in other R&D related costs.

General and administrative expenses were $1.6 million and $1.3 million, respectively for the quarters ended March 31, 2024 and 2023. The increase in general and administrative expenses was a result of an increase in business development expenses and in other various general and administrative expenses. These increases were offset by a decrease in various administrative consulting fees, a decrease in corporate insurance expense, a decrease in personnel salaries and benefits, and a decrease in legal fees.

As of March 31, 2024, Lipocine had $24.6 million of unrestricted cash, cash equivalents and marketable investment securities compared to $22.0 million at December 31, 2023.

**About Lipocine**

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery to develop differentiated products for CNS disorders. 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 combination of anabolic androgen receptor agonist and α-tocopherol, an antioxidant, as an adjunct therapy to incretin mimetics as an aid for improved body composition in chronic weight management and LPCN 1148, a novel androgen receptor agonist prodrug for oral administration targeted for the management of symptoms associated with liver cirrhosis including prevention of the recurrence of overt hepatic encephalopathy. Lipocine is exploring partnership opportunities for LPCN 1107, our candidate for prevention of preterm birth, LPCN 1154, for rapid relief of postpartum depression, LPCN 1148, for the management of decompensated cirrhosis, LPCN 2401 for obesity management and LPCN 1144, our candidate for treatment of non-cirrhotic NASH. 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 development efforts, our strategic plans for developing products to treat CNS disorders, our ability to monetize product candidates, including through entering into partnering arrangements, the application of our proprietary platform in developing new treatments for CNS disorders, our product candidates and related clinical trials, the achievement of milestones within and completion of clinical trials, the timing and completion of regulatory reviews, outcomes of clinical trials of our product candidates, 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 to treat CNS disorders, we may not have sufficient capital to complete the development processes for our product candidates, we may not be able to enter into partnerships or other strategic relationships to monetize our non-core assets, the FDA will 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

| | March 31, 2024 | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 3,081,337 | $ 4,771,758 |
| Marketable investment securities | 21,550,661 | 17,263,788 |
| Accrued interest income | 100,134 | 52,254 |
| Prepaid and other current assets | 583,087 | 773,424 |
| Total current assets | 25,315,219 | 22,861,224 |
| Property and equipment, net of accumulated depreciation of $1,190,703 and $1,182,191 respectively | 107,583 | 116,095 |
| Other assets | 23,753 | 23,753 |
| Total assets | $ 25,446,555 | $ 23,001,072 |

| Liabilities and Stockholders' Equity | | |
|---|---|---|
| Current liabilities: | | |
| Accounts payable | $ 671,445 | $ 1,395,977 |
| Accrued expenses | 761,465 | 1,218,486 |
| Warrant liability - current portion | 57,238 | 17,166 |
| Total current liabilities | 1,490,148 | 2,631,629 |
| Total liabilities | 1,490,148 | 2,631,629 |
| Stockholders' equity: | | |
| Common stock, par value $0.0001 per share, 200,000,000 shares authorized;5,316,166 issued and 5,315,830 outstanding | 8,860 | 8,860 |
| Additional paid-in capital | 220,262,456 | 220,171,250 |
| Treasury stock at cost, 336 shares | (40,712) | (40,712) |
| Accumulated other comprehensive gain (loss) | (10,604) | 7,259 |
| Accumulated deficit | (196,263,593) | (199,777,214) |
| Total stockholders' equity | 23,956,407 | 20,369,443 |
| Total liabilities and stockholders' equity | $ 25,446,555 | $ 23,001,072 |

**LIPOCINE INC. AND SUBSIDIARIES**

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

| | Three Months Ended March 31, | |
|---|---|---|
| | 2024 | 2023 |
| Revenues: | | |
| License revenue | $ 7,500,000 | $ 54,990 |
| Royalty revenue | 117,174 | - |
| Total revenues | 7,617,174 | 54,990 |
| Operating expenses: | | |
| Research and development | 2,818,926 | 3,106,310 |
| General and administrative | 1,575,719 | 1,287,313 |
| Total operating expenses | 4,394,645 | 4,393,623 |
| Operating income (loss) | 3,222,529 | (4,338,633) |
| Other income (expense): | | |
| Interest and investment income | 331,364 | 370,469 |
| Unrealized gain (loss) on warrant liability | (40,072) | 98,134 |
| Total other income, net | 291,292 | 468,603 |
| Income (loss) before income tax expense | 3,513,821 | (3,870,030) |
| Income tax expense | (200) | (200) |
| Net income (loss) | 3,513,621 | (3,870,230) |
| Issuance of Series B preferred stock dividend | - | (89) |
| Net income (loss) attributable to common shareholders | $ 3,513,621 | $ (3,870,319) |
| Basic income (loss) per share attributable to common stock | $ 0.66 | $ (0.74) |
| Weighted average common shares outstanding, basic | 5,315,830 | 5,234,830 |
| Diluted income (loss) per share attributable to common stock | $ 0.66 | $ (0.76) |
| Weighted average common shares outstanding, diluted | 5,357,530 | 5,234,830 |
| Comprehensive loss: | | |
| Net income (loss) | $ 3,513,621 | $ (3,870,319) |

| | | |
|---|---|---|
| Net unrealized gain (loss) on available-for-sale securities | (17,863) | 23,562 |
| Comprehensive income (loss) | $ 3,495,758 | $ (3,846,757) |

SOURCE Lipocine Inc.

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