# Lipocine Announces Financial Results for the Second Quarter Ended June 30, 2022

SALT LAKE CITY, Aug. 8, 2022 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on developing innovative products to treat metabolic and central nervous system ("CNS") disorders, today announced financial results for the second quarter ended June 30, 2022 and provided a corporate update.

**Second Quarter Highlights**

- In June, Lipocine's commercial partner Halozyme launched TLANDO™ (testosterone undecanoate), an oral treatment indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone (primary or hypogonadotropic hypogonadism).
- In July 2022, Lipocine held an End of Phase 2 meeting with the FDA for LPCN 1144 in NASH. The FDA recommends Lipocine conduct a phase 2 dose ranging study to identify the optimal dose prior to conducting a pivotal study. The FDA agreed to the proposed unique testosterone ester, testosterone dodecanoate, for future clinical studies.
- LPCN 1111: Technology transfer for our once-a-day testosterone product candidate was completed. Scale up and manufacturing of registration batches is ongoing.
- Lipocine continues to enroll subjects in a Phase 2 proof-of-concept study to evaluate the therapeutic potential of LPCN 1148 for the management of cirrhosis, with enrollment in the study expected to be complete in the second half of 2022.
- A type C meeting was held with the FDA to discuss the clinical development path of LPCN 1154, our candidate for postpartum depression ("PPD"). Based on feedback from the meeting, the company plans to initiate a multi-dose proof-of-concept study of LPCN 1154 in the second half of 2022.
- The FDA accepted the company's Investigational New Drug Application ("IND") for its neuroactive steroid ("NAS") candidate, LPCN 2101, as a potential treatment for adults with epilepsy. Lipocine plans to initiate a Phase 2 photosensitive epilepsy ("PSE") study to evaluate the safety, tolerability, and efficacy of oral LPCN 2101 in women with epilepsy of childbearing age.

We continue to explore partnering LPCN 1111, LPCN 1144, LPCN 1107 and TLANDO™ ex-US to third parties.

**Second Quarter Ended June 30, 2022 Financial Results**

Lipocine reported a net loss of $2.6 million, or ($0.04) per diluted share for the quarter ended June 30, 2022, compared with a net loss of $6.8 million, or ($0.08) per diluted share, in the quarter ended June 30, 2021.

Revenues in the quarter ended June 30, 2022 were $0.5 million related to a non-refundable cash fee received from Antares for consideration of a 90-day extension to exercise its option to license LPCN 1111. Antares' option to license TLANDO XR expired on June 30, 2022 and was not exercised. There was no revenue in the comparable quarter of 2021.

Research and development expenses were $2.9 million for the quarter ended June 30, 2022, compared with $1.5 million for the quarter ended June 30, 2021. The increase in research and development expenses for the quarter ended June 30, 2022, was a result of an increase in contract research organization expense related to the Phase 2 POC study in male cirrhotic subjects with LPCN 1148, an increase in costs related to LPCN 1154 clinical studies, increases in personnel expenses, and an increase in costs related to LPCN 1111 scale up and LPCN 1107 expenses. These increases were offset by a decrease in contract research organization expenses and outside consulting costs related to the completion of the LiFT Phase 2 clinical study in NASH subjects in 2021, a decrease in costs associated with TLANDO, as well as a decrease in other R&D expenses.

General and administrative expenses were $1.1 million for the quarter ended June 30, 2022, compared with $1.5 million for the quarter ended June 30, 2021. The decrease in general and administrative expenses was primarily due to decreases in legal expenses and personnel costs. These decreases were offset by an increase in professional fees, an increase related to proxy solicitation and proxy distribution services, an increase in corporate insurance expenses, and an increase in other general and administrative expenses.

As of June 30, 2022, the company had $37.4 million of unrestricted cash, cash equivalents and marketable investment securities, compared to $46.6 million at December 31, 2021.

**Six Months Ended June 30, 2022 Financial Results**

Lipocine reported a net loss of $6.1 million, or ($0.07) per diluted share, for the six months ended June 30, 2022, compared with a net loss of $10.2 million, or ($0.12) per diluted share, in the six months ended June 30, 2021.

Revenues in the six months ended June 30, 2022 were $0.5 million related to a non-refundable cash fee received from Antares for consideration of a 90-day extension to exercise its option to license LPCN 1111, as described above. There was no revenue in the comparable period of 2021.

Research and development expenses for the six months endedJune 30, 2022, were $4.8 million compared to $3.0 million for the comparable period in 2021. The increase in research and development expenses was due to an increase in contract research organization expense related to the Phase 2 POC study in male cirrhotic subjects with LPCN 1148, an increase in costs related to LPCN 1154 clinical studies, an increase related to LPCN 1111 scale up activities, a food effect study in LPCN 1107, and an increase in personnel expenses and other research and development costs. These increases were offset by a decrease in contract research organization expense and outside consulting costs related to the completion of our LPCN 1144 LiFT Phase 2 clinical study in NASH subjects in 2021, and a decrease in costs associated with TLANDO.

General and administrative expenses for the six months endedJune 30, 2022 were $2.4 million compared to $3.1 million for the comparable period in 2021. The decrease in general and administrative expenses was primarily due to decreases in legal expenses, personnel costs, and other general and administrative expenses. These decreases were offset by an increase in professional fees, an increase related to proxy solicitation and proxy distribution services, an increase in various other consulting fees, and an increase in corporate insurance expenses.

**About Lipocine**

Lipocine is biopharmaceutical company leveraging its commercially validated proprietary technology to develop innovative products to treat metabolic and CNS disorders with high unmet medical need. Our candidates target diseases with potential for orphan drug designation, comprise endogenous actives for favorable benefit to risk profile, and represent enablement of patient friendly oral delivery options. Lipocine's clinical development pipeline includes: LPCN 1148, LPCN 1144, LPCN 1111, LPCN 1107 and oral neuroactive steroids including LPCN 1154 and LPCN 2101. TLANDO™, a novel oral prodrug of testosterone containing testosterone undecanoate, is approved by the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the management of symptoms associated with liver cirrhosis. LPCN 1144, an oral prodrug of bioidentical testosterone, recently completed a Phase 2 clinical study demonstrating potential utility in the treatment of non-cirrhotic NASH. LPCN 1111, a novel oral prodrug of testosterone, originated and is being developed by Lipocine as a next-generation oral testosterone product with potential for once-daily dosing. In a phase 2 clinical evaluation when administered as once or twice daily, LPCN 1111 met primary and secondary endpoints. LPCN 1107 is potentially the first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth and has been granted orphan drug designation by the FDA. Neuroactive steroids are currently being evaluated including LPCN 1154 for the potential treatment of postpartum depression and LPCN 2101 for the potential treatment of epilepsy. 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 Lipocine's 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, the potential uses and benefits of our product candidates, the timing and scope of clinical trials and studies, and our product development efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that 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, 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.

*TLANDO® is a registered trademark assigned to Antares Pharma.

**LIPOCINE INC. AND SUBSIDIARIES**
Condensed Consolidated Balance Sheets
(Unaudited)

| | June 30, 2022 | December 31, 2021 |
|---|---|---|
| Current assets: | | |
| Cash and cash equivalents | $ 4,981,193 | $ 2,950,552 |
| Marketable investment securities | 32,414,473 | 41,667,405 |
| Accrued interest income | 80,411 | 247,253 |
| Prepaid and other current assets | 603,546 | 1,514,465 |

| | | |
|---|---|---|
| Total current assets | 38,079,623 | 46,379,675 |
| Marketable investment securities | - | 2,021,800 |
| Contract asset | 4,050,000 | 4,050,000 |
| Property and equipment, net of accumulated depreciation of $1,148,374 and $1,144,077 | 40,013 | 7,211 |
| Other assets | 23,753 | 23,753 |
| Total assets | $ 42,193,389 | $ 52,482,439 |
| Current liabilities: | | |
| Accounts payable | $ 814,004 | $ 1,289,342 |
| Accrued expenses | 899,301 | 1,016,458 |
| Debt - current portion | - | 2,310,825 |
| Litigation settlement liability - current portion | - | 1,000,000 |
| Total current liabilities | 1,713,305 | 5,616,625 |
| Warrant liability | 590,339 | 795,796 |
| Litigation settlement liability - non-current portion | - | 500,000 |
| Total liabilities | 2,303,644 | 6,912,421 |
| Stockholders' equity: | | |
| Preferred stock, par value $0.0001 per share, 10,000,000 shares authorized; zero issued and outstanding | - | - |
| Common stock, par value $0.0001 per share, 200,000,000 shares authorized; 88,504,834 and 88,296,360 issued and 88,499,124 and 88,290,650 outstanding | 8,850 | 8,829 |
| Additional paid-in capital | 218,792,479 | 218,286,324 |
| Treasury stock at cost, 5,710 shares | (40,712) | (40,712) |
| Accumulated other comprehensive loss | (84,907) | (18,016) |
| Accumulated deficit | (178,785,965) | (172,666,407) |
| Total stockholders' equity | 39,889,745 | 45,570,018 |
| Total liabilities and stockholders' equity | $ 42,193,389 | $ 52,482,439 |

**LIPOCINE INC. AND SUBSIDIARIES**

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Revenues: | $ 500,000 | $ - | $ 500,000 | $ - |
| Operating expenses: | | | | |
| Research and development | 2,898,012 | 1,464,687 | 4,785,965 | 3,045,228 |
| General and administrative | 1,129,519 | 1,525,592 | 2,373,205 | 3,059,544 |
| Total operating expenses | 4,027,531 | 2,990,279 | 7,159,170 | 6,104,772 |
| Operating loss | (3,527,531) | (2,990,279) | (6,659,170) | (6,104,772) |
| Other income (expense): | | | | |
| Interest and investment income | 69,877 | 17,344 | 111,453 | 27,993 |
| Interest expense | (7,568) | (57,428) | (27,098) | (126,401) |
| Unrealized gain on warrant liability | 583,445 | 221,322 | 205,457 | 26,257 |
| Gain (loss) litigation settlement liability | 250,000 | (4,000,000) | 250,000 | (4,000,000) |

| | | | | |
|---|---|---|---|---|
| Total other income (expense), net | 895,754 | (3,818,762) | 539,812 | (4,072,151) |
| Loss before income tax expense | (2,631,777) | (6,809,041) | (6,119,358) | (10,176,923) |
| Income tax expense | - | - | (200) | (200) |
| Net loss | $ (2,631,777) | $ (6,809,041) | $ (6,119,558) | $ (10,177,123) |
| Basic loss per share attributable to common stock | $ (0.03) | $ (0.08) | $ (0.07) | $ (0.12) |
| Weighted average common shares outstanding, basic | 88,499,067 | 88,290,650 | 88,404,999 | 85,556,110 |
| Diluted loss per share attributable to common stock | $ (0.04) | $ (0.08) | $ (0.07) | $ (0.12) |
| Weighted average common shares outstanding, diluted | 88,998,515 | 88,988,292 | 88,987,800 | 86,294,935 |
| Comprehensive loss: | | | | |
| Net loss | $ (2,631,777) | $ (6,809,041) | $ (6,119,558) | $ (10,177,123) |
| Net unrealized gain (loss) on available-for-sale securities | (17,491) | 22,273 | (66,891) | (186) |
| Comprehensive loss | $ (2,649,268) | $ (6,786,768) | $ (6,186,449) | $ (10,177,309) |

SOURCE Lipocine Inc.

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