# Lipocine Announces Financial Results for the Year Ended December 31, 2021

SALT LAKE CITY, March 9, 2022 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on neuroendocrine and metabolic disorders, today announced financial results for the fourth quarter and year ended December 31, 2021 and provided a corporate update.

**Clinical Program Highlights**

LPCN 1148

- Initiated a Phase 2 proof-of-concept clinical study evaluating LCPN 1148 for the management of decompensated liver cirrhosis in patients on the transplant waitlist
    - We currently expect enrollment in the Phase 2 study to be complete by the end of the second or third quarter of 2022 and top-line 24-week results by the end of 2022 or during the first quarter of 2023.

LPCN 1144

- In August 2021, Lipocine announced positive topline 36-week results from its Phase 2 proof of concept *LiFT* ("***L***iver ***F***at intervention with oral ***T***estosterone") clinical study investigating LPCN 1144 in men with biopsy-confirmed NASH. Key secondary endpoints post 36 weeks of treatment include assessment of histological change for NASH resolution and/or fibrosis improvement.
- Lipocine held a Type C meeting with the U.S. Food and Drug Administration ("FDA") to discuss the clinical development path for LPCN 1144 in non-cirrhotic non-alcoholic steatohepatitis ("NASH"). The FDA suggested a Phase 3 trial with a primary multicomponent surrogate endpoint and indicated a study duration of 72 weeks would be adequate for seeking approval under an accelerated pathway, if successful.

TLANDO®

- Lipocine entered into a license agreement with Antares Pharma in 2021 to commercialize TLANDO in the U.S.
    - The FDA accepted a New Drug Application ("NDA") resubmission for TLANDO® (testosterone undecanoate) and designated the NDA as a Class 1 resubmission with a two-month review goal period and set a target action date of March 28, 2022, under the Prescription Drug User Fee Act ("PDUFA").

Neuroactive Steroids

- The FDA has cleared an investigational new drug ("IND") application to conduct a Phase 2 proof of concept study of LPCN 1154, an oral endogenous neuroactive steroid ("NAS") product candidate, in postpartum depression.
- An IND application is planned to be filed with the FDA in the second quarter of 2022 for LPCN 2101 to conduct and IND opening proof-of-concept study in women with epilepsy of childbearing age.

**Year Ended December 31, 2021 Financial Results**

Lipocine reported a net loss of $634,399, or ($0.01) per diluted share, for the year ended December 31, 2021, compared with a net loss of $21 million, or ($0.38) per diluted share, in the year ended December 31, 2020.

Lipocine recognized revenue of $16.1 million during the year ended December 31, 2021, compared to no revenue during the year ended December 31, 2020. Revenue in 2021 primarily related to licensing fees, minimum royalties and the sale of finished goods materials we received in accordance with the Antares Licensing Agreement for TLANDO which was signed on October 14, 2021.

Research and development expenses were $7.7 million for the year ended December 31, 2021, compared with $9.7 million for the year ended December 31, 2020. The decrease in research and development expenses during the year ended December 31, 2021 was primarily due a decrease in contract research organization expense and outside consulting costs related to the LPCN 1144 LiFT Phase 2 clinical study in NASH subjects, a decrease in costs associated with TLANDO and a net decrease in personnel expense, as well as decreases in other R&D expenses. These decreases were offset by increases in costs related to LPCN 1154, LPCN 1148 and LPCN 1107.

General and administrative expenses were $5.3 million for the year ended December 31, 2021, compared with $8.2 million for the year ended December 31, 2020. The decrease in general and administrative expenses

during the year ended December 31, 2021 was primarily due to decreases in legal costs and personnel costs, offset by an increase in corporate insurance expenses and in other general and administrative expenses.

Lipocine recorded an expense of $4.0 million on litigation settlement during 2021 related to the Global Agreement with Clarus to resolve all outstanding claims in the on-going intellectual property litigation between the two companies as well as the on-going interference proceeding between the two companies. There was no comparable litigation settlement expense in 2020.

As of December 31, 2021, Lipocine had $44.6 million of unrestricted cash, cash equivalents, and marketable investments, compared to $19.7 million of unrestricted cash, cash equivalents and marketable investment securities as of December 31, 2020.

**About Lipocine**
Lipocine Inc. is a clinical-stage biopharmaceutical company focused on endocrine and metabolic disorders using its proprietary drug delivery technologies. Lipocine's clinical development pipeline includes: LPCN 1154, LPCN 2021, LPCN 1148, LPCN 1111, LPCN 1144, and LPCN 1107. LPCN 1154 is an oral neuroactive steroid targeted for the treatment of post-partum depression and LPCN 2101 is an oral neuroactive steroid targeted for the treatment of women of childbearing age with epilepsy. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the management of symptoms associated with liver cirrhosis. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, has received tentative approval from the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males and has been licensed for commercialization to Antares. 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 the typical primary and secondary endpoints. 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 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. 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 timing of completion of clinical trials and studies, the timing and completion of regulatory reviews, outcomes of clinical trials of our product candidates, the potential uses and benefits of our product candidates, 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.

**LIPOCINE INC. AND SUBSIDIARIES**
Consolidated Balance Sheets
December 31, 2021 and 2020

| | 2021 | 2020 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 2,950,552 | $ 19,217,382 |
| Restricted cash | - | 5,000,000 |
| Marketable investment securities | 41,667,405 | 449,992 |
| Accrued interest income | 247,253 | 391 |
| Prepaid and other current assets | 1,514,465 | 661,258 |
| Total current assets | 46,379,675 | 25,329,023 |
| Marketable investment securities | 2,021,800 | - |
| Contract asset | 4,050,000 | - |
| Property and equipment, net of accumulated depreciation | | |

| | | |
|---|---|---|
| of $1,144,077 and $1,143,697 respectively | 7,211 | - |
| Other assets | 23,753 | 23,753 |
| Total assets | $ 52,482,439 | $ 25,352,776 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,289,342 | $ 1,597,220 |
| Accrued expenses | 1,016,458 | 1,653,178 |
| Debt - current portion | 2,310,825 | 3,333,333 |
| Litigation settlement liability - current portion | 1,000,000 | - |
| Total current liabilities | 5,616,625 | 6,583,731 |
| Debt - non-current portion | - | 2,257,075 |
| Warrant liability | 795,796 | 1,170,051 |
| Litigation settlement liability - non-current portion | 500,000 | - |
| Total liabilities | 6,912,421 | 10,010,857 |
| Commitments and contingencies | | |
| 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, 100,000,000 shares authorized; 88,296,360 and 70,041,967 issued and 88,290,650 and 70,036,257 outstanding | 8,830 | 7,005 |
| Additional paid-in capital | 218,286,323 | 187,407,634 |
| Treasury stock at cost, 5,710 shares | (40,712) | (40,712) |
| Accumulated other comprehensive loss | (18,016) | - |
| Accumulated deficit | (172,666,407) | (172,032,008) |
| Total stockholders' equity | 45,570,018 | 15,341,919 |
| Total liabilities and stockholders' equity | $ 52,482,439 | $ 25,352,776 |

**LIPOCINE INC. AND SUBSIDIARIES**

Consolidated Statements of Operations and Comprehensive Loss

Years Ended December 31, 2021 and 2020

| | 2021 | 2020 |
|---|---|---|
| Revenues | $ 16,140,838 | $ - |
| Operating expenses: | | |
| Research and development | 7,665,559 | 9,748,469 |
| General and administrative | 5,329,776 | 8,247,795 |
| Total operating expenses | 12,995,335 | 17,996,264 |
| Operating income (loss) | 3,145,503 | (17,996,264) |
| Other income (expense) | | |
| Interest and investment income | 67,700 | 75,650 |
| Interest expense | (203,292) | (386,618) |
| Gain on extinguishment of debt | - | 234,802 |
| Unrealized gain (loss) on warrant liability | 355,890 | (2,892,189) |
| Litigation settlement | (4,000,000) | - |

| | | |
|---|---|---|
| Total other expense, net | (3,779,702) | (2,968,355) |
| Loss before income tax expense | (634,199) | (20,964,619) |
| Income tax expense | (200) | (200) |
| Net loss | $ (634,399) | $ (20,964,819) |
| Basic loss per share attributable to common stock | $ (0.01) | $ (0.38) |
| Weighted average common shares outstanding, basic | 86,934,618 | 55,688,085 |
| Diluted loss per share attributable to common stock | $ (0.01) | $ (0.38) |
| Weighted average common shares outstanding, diluted | 86,934,618 | 55,688,085 |
| Comprehensive loss: | | |
| Net loss | $ (634,399) | $ (20,964,819) |
| Unrealized net gain (loss) on available-for-sale securities | (18,016) | 38 |
| Comprehensive loss | $ (652,415) | $ (20,964,781) |

SOURCE Lipocine Inc.

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https://ir.lipocine.com/2022-03-09-Lipocine-Announces-Financial-Results-for-the-Year-Ended-December-31,-2021