Lipocine Announces Financial Results for the Third Quarter Ended September 30, 2024

SALT LAKE CITY, Nov. 7, 2024 /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 and nine months ended September 30, 2024 and provided a corporate update.

Neuroactive Steroids

- LPCN 1154, oral brexanolone, is being developed as a treatment for postpartum depression (PPD). It is targeted to be a highly effective, oral, fast-acting and short duration treatment option.
- The Company has completed labeling studies such as a food effect study and PK profiling in women with PPD, and is targeting NDA submission for LPCN 1154 by the end of 2024.
- In October, Lipocine announced positive results from a quantitative electroencephalogram (qEEG) study conducted in healthy subjects administered single doses of LPCN 1154. The results indicated robust central nervous system (CNS) activity of LPCN 1154, with concentration- and time-dependent post-dose changes in qEEG. The study confirmed $GABA_A$ positive allosteric modulation and supports future development of LPCN 1154 in neuropsychiatric indications.

LPCN 2401 for obesity management

- LPCN 2401 is an oral formulation comprised of a proprietary anabolic androgen receptor agonist targeted for once daily regimen.
- In October, Lipocine hosted a virtual key opinion leader (KOL) event on LPCN 2401.
    - The event highlighted positive data from the Phase 2 study of LPCN 2401 and the data support the potential for the product to be used as an adjunct with incretin mimetics (GLP-1/GIP agonists) or as a monotherapy, including post incretin mimetic discontinuation.
    - Frank Greenway, MD (Professor and Chief Medical Officer at Pennington Biomedical Research Center) discussed the unmet needs and current treatment landscape in obesity management with a focus on fat loss and lean muscle mass preservation for patients on incretin therapies.
- A poster "Oral LPCN 2401 Reduces Fat Mass and Increases Lean Mass in Men With Obesity" featuring the Phase 2 data was presented by Dr. Greenway at the Obesity Society's Annual ObesityWeek® conference on November 5, 2024 in San Antonio, TX.
- Lipocine plans to meet with the FDA to discuss the study design for a proof-of-concept Phase 2 study for LPCN 2401 and expansion to the female population.

LPCN 1148 Management of Cirrhosis

- Lipocine is evaluating LPCN 1148 for the management of decompensated cirrhosis and has conducted a successful Phase 2 study that met its primary endpoint. The Company plans to request a Type C meeting with the FDA to discuss the clinical development plan for LPCN 1148.

TLANDO®

- In October, Lipocine signed an exclusive supply and distribution agreement with Pharmalink to commercialize TLANDO, its oral testosterone replacement therapy, in the Gulf Cooperation Council (GCC) countries consisting of Saudi Arabia, Kuwait, the United Arab Emirates (UAE), Qatar, Bahrain, and Oman.
- In September, Lipocine signed an exclusive distribution and license agreement with SPC Korea to commercialize TLANDO in South Korea.

The company continues to pursue opportunities for partnering and/or development arrangements for the continued development and/or marketing of our remaining pipeline candidates.

Third Quarter Ended September 30, 2024 Financial Results

Lipocine reported a net loss of $2.2 million, or ($0.44) per diluted share, for the third quarter ended September 30, 2024, compared with a net loss of $6.7 million, or ($1.27) per diluted share, for the quarter ended September 30, 2023.

There were no revenues recorded during the third quarter ended September 30, 2024. In the third quarter of 2023, the company recorded a non-cash revenue reversal of variable consideration for minimum guaranteed royalties of $3.1 million related to the termination of the Antares License Agreement.

Research and development expenses were $1.6 million and $2.9 million, respectively, for the quarters ended September 30, 2024 and 2023. The decrease was a result of a decrease in TLANDO related costs, a decrease in contract research organization expense and outside consulting costs related to the wind down of the LPCN 1148 study in 2024, and a decrease in costs related to LPCN 1154 clinical studies, offset by increases in personnel related costs and other research and development related costs and supplies.

General and administrative expenses were $1.0 million in each of the quarters ended September 30, 2024 and 2023.

As of September 30, 2024, Lipocine had $19.8 million of unrestricted cash, cash equivalents and marketable investment securities compared to $22.0 million at December 31, 2023.

Nine Months Ended, September 30 2024, Financial Results

Lipocine reported a net loss of $1.8 million, or ($0.33) per diluted share, for the nine months ended September 30, 2024, compared with a net loss of $14.1 million, or ($2.72) per diluted share, for the nine months ended September 30, 2023.

Revenues for the nine-month period ended September 30, 2024 were $7.7 million, primarily consisting of licensing revenue received from our Verity License Agreement, in addition to TLANDO royalty revenue of $206,000. During the nine months ended September 30, 2023, the company recognized a non-cash revenue reversal of variable consideration for minimum guaranteed royalties of $3.1 million relating to the termination of the Antares License Agreement offset by licensing revenue of approximately $55,000 for payments received related to the Spriaso license agreement.

Research and development expenses were $6.3 million and $8.5 million, respectively, for the nine months ended September 30, 2024 and 2023. The decrease was a result of a decrease in contract research organization expense and outside consulting costs related to the wind down of the LPCN 1148 study in 2024, a decrease in TLANDO related costs, a decrease in personnel related costs, and a decrease in other research and development related costs. These decreases were offset an increase in costs related to the LPCN 1154 clinical studies.

General administrative expenses were $4.1 million and $3.8 million respectively, for the nine months ended September 30, 2024 and 2023. The increase in general and administrative expenses was a result of increases in business development expenses, corporate legal fees and director fees, offset by decreases in corporate insurance expense, professional fees, other administrative consulting fees, personnel related costs, and travel related costs.

For more information on Lipocine's financial results, refer to Form 10-Q filed by the Company with the SEC.

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery to develop differentiated products. 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 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 development and commercialization of TLANDO and TLANDO XR by our licensees, the amount of the license fee, milestone payments, and royalty payments we will ultimately receive, the ability of our licensees to grow the TLANDO franchise, our product development efforts, the application of our proprietary platform in developing new treatments for CNS disorders, our product candidates and related clinical trials, our development of our product candidates and related efforts with the FDA, including with respect to LPCN 1148 and LPCN 2401, the timing of our submission of a NDA with the FDA for LPCN 1154, 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
(Unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 3,742,941	$ 4,771,758
Marketable investment securities	16,080,691	17,263,788
Accrued interest income	91,482	52,254
Prepaid and other current assets	588,824	773,424
Total current assets	20,503,938	22,861,224
Property and equipment, net of accumulated depreciation of $1,207,726 and $1,182,191 respectively	170,627	116,095
Other assets	23,753	23,753

Total assets	$ 20,698,318	$ 23,001,072
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 285,347	$ 1,395,977
Accrued expenses	1,292,285	1,218,486
Warrant liability	3,586	17,166
Total current liabilities	1,581,218	2,631,629
Total liabilities	1,581,218	2,631,629
Stockholders' equity:		
Common stock, par value $0.0001 per share, 200,000,000 shares authorized; 5,348,276 and 5,316,166 issued, and 5,347,940 and 5,315,830 outstanding, respectively outstanding	8,863	8,860
Additional paid-in capital	220,690,052	220,171,250
Treasury stock at cost, 336 shares	(40,712)	(40,712)
Accumulated other comprehensive gain (loss)	9,942	7,259
Accumulated deficit	(201,551,045)	(199,777,214)
Total stockholders' equity	19,117,100	20,369,443
Total liabilities and stockholders' equity	$ 20,698,318	$ 23,001,072

LIPOCINE INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
License revenue	$ -	$ -	$ 7,500,000	$ 54,990
Royalty revenue	-	-	206,738	-
Minimum guaranteed royalties revenue (reversal of variable consideration)	-	(3,121,996)	-	(3,121,996)
Total revenues	-	(3,121,996)	7,706,738	(3,067,006)
Operating expenses:				
Research and development	1,585,233	2,878,798	6,278,881	8,500,319
General and administrative	1,045,240	1,042,572	4,128,371	3,770,281
Total operating expenses	2,630,473	3,921,370	10,407,252	12,270,600
Operating loss	(2,630,473)	(7,043,366)	(2,700,514)	(15,337,606)
Other income:				
Interest and investment income	273,574	317,569	913,784	1,067,561
Unrealized gain on warrant liability	138,081	74,827	13,580	200,416
Total other income	411,655	392,396	927,364	1,267,977
Loss before income tax expense	(2,218,818)	(6,650,970)	(1,773,150)	(14,069,629)
Income tax expense	-	-	(681)	(200)
Net loss	(2,218,818)	(6,650,970)	(1,773,831)	(14,069,829)
Issuance of Series B preferred stock dividend	-	-	-	(89)
Net loss attributable to common shareholders	$ (2,218,818)	$ (6,650,970)	$ (1,773,831)	$ (14,069,918)
Basic loss per share attributable to common stock	$ (0.41)	$ (1.26)	$ (0.33)	$ (2.68)

Weighted average common shares outstanding, basic	5,347,940	5,292,058	5,335,941	5,254,116
Diluted loss per share attributable to common stock	$ (0.44)	$ (1.27)	$ (0.33)	$ (2.72)
Weighted average common shares outstanding, diluted	5,347,940	5,292,058	5,335,941	5,254,116
Comprehensive loss:				
Net loss	$ (2,218,818)	$ (6,650,970)	$ (1,773,831)	$ (14,069,829)
Net unrealized gain on marketable investment securities	19,661	1,309	2,683	5,818
Comprehensive loss	$ (2,199,157)	$ (6,649,661)	$ (1,771,148)	$ (14,064,011)

SOURCE Lipocine Inc.

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