Lipocine Investor Room

Lipocine Announces Financial Results for the Second Quarter Ended June 30, 2024

SALT LAKE CITY, Aug. 8, 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 second quarter ended June 30, 2024 and provided a corporate update.

LPCN 1154 for Postpartum Depression (PPD)

- In June 2024, Lipocine announced positive topline study results from the NDA enabling study of LPCN 1154. LPCN 1154 treatment was well tolerated with no sedation nor somnolence events observed
- The Company is targeting NDA submission for LPCN 1154 by the end of the fourth quarter of 2024
- LPCN 1154, oral brexanolone, is being developed as a 48-hour oral dosing duration treatment for treatment of postpartum depression. It is targeted to be a highly effective, fast-acting and outpatient treatment option

LPCN 2401 for Chronic Weight Management

- In April 2024, the Company announced positive results from the multi-center perspective, 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
- LPCN 2401 treatment resulted in significant improvements in body composition through increased lean mass (LM) or fat free mass (FFM) and bone mineral content in addition to decreased fat mass (FM) and android fat. LPCN 2401 was well-tolerated; adverse events (AEs) including GI events were similar to placebo with no muscle spasm reported
- LPCN 2401 has potential for use in combination with incretin mimetics (GLP-1/GIP agonists) including amplification of GLP-1R insulinotropic actions supported by studies demonstrating the role of the androgen receptor agonist in regulation of GLP-1R. Target benefits of LPCN 2401 in combination with GLP-1 agonists include improved body composition with quality weight loss while attenuating lean mass loss, a serious unmet need, and quality fat loss through appreciable abdominal fat loss. LPCN 2401 could also be potentially used as monotherapy post discontinuation of GLP-1 agonist to manage weight/fat regain and durability of diabetes remission
- Lipocine plans to meet with FDA to discuss the further development of LPCN 2401 as an aid to weight management interventions

LPCN 1148 for Management of Cirrhosis

- In June, results from a Phase 2 study evaluating LPCN 1148 in cirrhosis were featured in a late breaking oral presentation at the European Association for the Study of Liver (EASL) Congress. The presentation was delivered by Arun J. Sanyal, MD, Director, Stravitz-Sanyal Institute for Liver Disease and Metabolic Health, Virginia Commonwealth University. The presentation was featured in the symposium "Revolutionary Advances in Liver Disease Research Unveiled at EASL Congress 2024" highlighting significant advances in liver disease
    - As previously announced, the study met primary and hepatic encephalopathy (HE) endpoints and LPCN 1148 was well-tolerated, with AE rates and severities similar to placebo

We continue to pursue opportunities for partnering and/or development arrangements for the continued development and/or marketing of our pipeline candidates.

Second quarter Ended June 30, 2024 Financial Results

Lipocine reported a net loss of $3.1 million, or ($0.56) per diluted share, for the second quarter ended June 30, 2024, compared with a net loss of $3.6 million, or ($0.68) per diluted share, for the quarter ended June 30, 2023.

Revenues were approximately $90,000, consisting of royalty revenue from the Verity license agreement in the second quarter of 2024. No revenue was recorded during the second quarter of 2023.

Research and development expenses were $1.9 million and $2.5 million, respectively, for the quarters ended June 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 our LPCN 1148 study in 2024, a decrease in TLANDO related costs, and a decrease in personnel related costs, offset by an increase in costs related to the LPCN 1154 clinical studies, and an increase in other R&D related costs.

General and administrative expenses were $1.5 million and $1.4 million, respectively for the quarters ended June 30, 2024 and 2023.

As of June 30, 2024, Lipocine had $22.5 million of unrestricted cash, cash equivalents and marketable investment securities compared to $22.0 million at December 31, 2023.

Six Months Ended, June 30 2024 Financial Results

Lipocine reported a net profit of $0.5 million, or $0.10 per diluted share, for the six months ended June 30, 2024, compared with a net loss of $7.4 million, or ($1.42) per diluted share, for the six months ended June 30, 2023.

Revenues for the six-month period ended June 30, 2024 were $7.7 million, primarily consisting of licensing revenue from the Verity License Agreement. This compares with licensing revenue of $55,000 during the six months ended June 30, 2023.

Research and development expenses were $4.7 million and $5.6 million, respectively, for the six months ended June 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 our LPCN 1148 study in 2024, decrease in personnel related costs, and a decrease in LPCN 1111 and LPCN 1144 clinical study costs. These decreases were offset by an increase in costs related to our LPCN 1154 clinical studies, an increase in TLANDO related costs, and an increase in other research and development related costs.

General administrative expenses were $3.1 million and $2.7 million, respectively, for the six months endedJune 30, 2024 and 2023.

For more information on Lipocine's financial results, refer to Form 10Q 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 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. 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 chronic weight 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 our product development efforts, our strategic plans for developing products, our ability to monetize product candidates, including through entering into partnering arrangements, 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, 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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 5,553,371	$ 4,771,758
Marketable investment securities	16,995,424	17,263,788
Accrued interest income	63,636	52,254
Prepaid and other current assets	297,051	773,424
Total current assets	22,909,482	22,861,224
Property and equipment, net of accumulated depreciation of $1,199,215 and $1,182,191 respectively	99,071	116,095
Other assets	23,753	23,753
Total assets	$ 23,032,306	$ 23,001,072
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 448,798	$ 1,395,977
Accrued expenses	1,233,477	1,218,486
Warrant liability	141,668	17,166
Total current liabilities	1,823,943	2,631,629

Total liabilities	1,823,943	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	220,582,158	220,171,250
Treasury stock at cost, 336 shares	(40,712)	(40,712)
Accumulated other comprehensive gain (loss)	(9,719)	7,259
Accumulated deficit	(199,332,227)	(199,777,214)
Total stockholders' equity	21,208,363	20,369,443
Total liabilities and stockholders' equity	$ 23,032,306	$ 23,001,072

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues:				
License revenue	$ -	$ -	$ 7,500,000	$ 54,990
Royalty revenue	89,565	-	206,738	-
Total revenues	89,565	-	7,706,738	54,990
Operating expenses:				
Research and development	1,874,721	2,515,211	4,693,646	5,621,521
General and administrative	1,507,412	1,440,394	3,083,131	2,727,708
Total operating expenses	3,382,133	3,955,605	7,776,777	8,349,229
Operating loss	(3,292,568)	(3,955,605)	(70,039)	(8,294,239)
Other income (expense):				
Interest and investment income	308,845	379,521	640,209	749,991
Unrealized gain (loss) on warrant liability	(84,430)	27,455	(124,502)	125,589
Total other income, net	224,415	406,976	515,707	875,580
Income (loss) before income tax expense	(3,068,153)	(3,548,629)	445,668	(7,418,659)
Income tax expense	(481)	-	(681)	(200)
Net income (loss)	(3,068,634)	(3,548,629)	444,987	(7,418,859)
Issuance of Series B preferred stock dividend	-	-	-	(89)
Net income (loss) attributable to common shareholders	$ (3,068,634)	$ (3,548,629)	$ 444,987	$ (7,418,948)
Basic earnings (loss) per share attributable to common stock	$ (0.57)	$ (0.68)	$ 0.08	$ (1.42)
Weighted average common shares outstanding, basic	5,343,922	5,234,830	5,329,876	5,234,830
Diluted earnings (loss) per share attributable to common stock	$ (0.56)	$ (0.68)	$ 0.10	$ (1.44)
Weighted average common shares outstanding, diluted	5,343,922	5,234,830	5,459,204	5,234,830
Comprehensive income (loss):				
Net income (loss)	$ (3,068,634)	$ (3,548,629)	$ 444,987	$ (7,418,859)
Net unrealized gain (loss) on marketable investment securities	885	(19,053)	(16,978)	4,509
Comprehensive income (loss)	$ (3,067,749)	$ (3,567,682)	$ 428,009	$ (7,414,350)

SOURCE Lipocine Inc.

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