Lipocine Announces Strategic Realignment and Forward Focus on Treating CNS Disorders

Company to apply its proprietary Lip'ral oral drug delivery technology to advance a pipeline of differentiated products for Central Nervous System (CNS) disorders

Initial focus on oral delivery of neuroactive steroids; important near-term clinical milestones for lead candidate LPCN 1154 for postpartum depression (PPD)

Company to explore strategic partnerships and other opportunities for non-core assets

SALT LAKE CITY, Sept. 26, 2022 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on leveraging its proprietary Lip'ral platform to develop differentiated products through the oral delivery of previously difficult to deliver molecules, announced today its plans to focus on treating CNS disorders.

"We are excited to announce a new strategic direction for Lipocine, which involves applying our validated Lip'ral technology to develop new treatments for CNS disorders," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "Our initial focus is on endogenous neuroactive steroids which have broad applicability in treating various CNS conditions and where we can leverage our platform to develop highly differentiated oral therapeutics."

"The changes we are implementing allow us to focus on a select number of candidates in active development and to manage our resources efficiently," continued Dr. Patel. "We continue to believe in the value of our non-core candidates and have determined that the optimal way to advance these assets will be through partnership. We believe that this strategy will allow us to diversify risk and can create opportunities for non-dilutive financing."

New Strategic Direction Focused on CNS

Lipocine's priority is to advance its pipeline of endogenous neuroactive steroids (NAS). NAS have been shown to impact central nervous system function largely through allosteric modulation of the $GABA_A$ receptor. As a novel drug class, NAS have received considerable attention because of their potential to treat various neuropsychiatric conditions including depression, movement disorders, epilepsy, anxiety, and neurodegenerative diseases.

Lipocine believes that its technology can be applied to enable effective oral delivery of endogenous modulators of the $GABA_A$ receptor, which historically have been challenging to deliver orally due to poor aqueous solubility. The CNS development portfolio includes LPCN 1154, a fast-acting oral antidepressant for postpartum depression (PPD) with potential for outpatient use; LPCN 2101, with a novel mechanism of action, for women with epilepsy; and additional undisclosed CNS-focused candidates.

Lipocine's most advanced NAS candidate is LPCN 1154, a non-invasive, oral formulation of the neurosteroid brexanolone which the company is developing for the treatment of PPD. Lipocine recently announced that the U.S. Food and Drug Administration ("FDA") has agreed with the Company's proposal for establishing the efficacy of LPCN 1154 through a pivotal pharmacokinetic ("PK") bridge to an approved IV infusion brexanolone via a 505(b)(2) NDA filing. The pilot PK bridge study (a prelude to a pivotal study required for NDA filing) is ongoing with results expected in the first quarter of 2023.

Planned Monetization of Non-Core Assets

Lipocine has developed a portfolio of clinical stage candidates including LPCN 1144 for treatment of non-cirrhotic NASH, LPCN 1148 for decompensated liver cirrhosis, LPCN 1107 for prevention of pre-term birth, and LPCN 1111, a once-a-day therapy for TRT. The Company intends to advance these programs further through partnerships, a strategy that is designed to diversify risk and potentially create opportunities for non-dilutive financing. As a result, no further significant investment is expected for these programs. The Company plans to complete the ongoing Phase 2 proof-of-concept study for LPCN 1148 in liver cirrhosis and continues to explore ex-U.S. commercialization of FDA approved TLANDO through partnering.

Lipocine had $37.4 million of unrestricted cash, cash equivalents and marketable investment securities, as of June 30, 2022. The Company believes that this cash will be sufficient to support operations and capital expenditure until at least September 30, 2023.

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery to develop products for CNS disorders. Lipocine has candidates in development and candidates for which we are exploring partnering which target large addressable markets with significant unmet medical needs. Our candidates represent enablement of patient friendly oral delivery options for favorable benefit to risk profile.

Lipocine clinical development candidates include: LPCN 1154, oral brexanolone, for the potential treatment of postpartum depression, LPCN 2101 for the potential treatment of epilepsy and LPCN 1148, an oral prodrug of bioidentical testosterone targeted for the management of symptoms associated with liver cirrhosis. Lipocine is exploring partnering LPCN 1144, our candidate for treatment of non-cirrhotic NASH, LPCN 1148, LPCN 1107, our candidate for prevention of pre-term birth, and LPCN 1111, a once-a-day therapy candidate for testosterone replacement therapy (TRT). 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 non-core product candidates, the application of our Lip'ral 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 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, 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.

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