Lipocine Announces Senior Leadership Appointments to Advance its CNS-Focused Pipeline

SALT LAKE CITY, Nov. 3, 2022 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on treating CNS disorders by leveraging its proprietary platform to develop differentiated products, today announced George Nomikos, M.D., Ph.D., has joined Lipocine as Chief Medical Officer and Spyros Papapetropoulos, M.D. Ph.D., has been appointed Lead Director and Chairman of the Board.

Lipocine Inc. 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 in postpartum depression through a pivotal pharmacokinetic ("PK") bridge study to an approved IV infusion brexanolone via a 505(b)(2) NDA filing. Lipocine recently initiated a pilot PK bridge study (a prelude to a pivotal study required for NDA filing) and expects to report results of the pilot study in the first half of 2023. If approved, LPCN 1154 is expected to be the fastest acting oral option for PPD with potential for out-patient use.

"Consistent with our recently announced new strategy to a focus on developing new treatments for CNS disorders, it is important that Lipocine have a leadership team with the appropriate skillset," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "I am delighted to welcome Dr. Nomikos as Chief Medical Officer and congratulate Dr. Papapetropoulos on his appointment as Lead Director and Chairman of the Board. George's knowledge in the fields of neurology and psychiatry, both from an academic and industry perspective, will be invaluable as we advance our pipeline of CNS candidates. In addition, Spyros' executive and BoD tenure in CNS-focused companies combined with his expertise in clinical and translational neurosciences means that he is well qualified to guide the company. We look forward to the contributions these talented individuals will bring to Lipocine and are excited to have them as an integral part of our leadership team."

Dr. Spyros Papapetropoulos commented, "This is an exciting time for Lipocine. The Company has a compelling opportunity to leverage its best-in-class oral delivery technology to develop differentiated treatments for high unmet need neuropsychiatric disorders. I look forward to continue being a part of the Company's renewed CNS focus in my role as Chairman."

Dr. George Nomikos stated, "I am very pleased to join Lipocine and to have the opportunity to leverage my expertise in neurology and psychiatry as I join a talented and dedicated team working to bring new treatments to patients."

George Nomikos, M.D., Ph.D. is a biopharmaceutical R&D scientist and psychiatry-trained clinician with extensive academic and industry experience in neuropsychiatric, neurometabolic, neurohormonal, neuromuscular and chronic pain therapeutics. He has a proven track record directing large cross-site and cross-functional teams to key advancement decisions in drug discovery research and clinical development. Until recently he served as SVP, Medical & Clinical Sciences at Scholar Rock, a clinical-stage biopharmaceutical company, where he oversaw clinical development and medical functions of neuromuscular therapeutics. Dr Nomikos previously held senior positions at Biogen, Sage, Takeda, Astellas, Amgen and Eli Lilly. He has directed a broad spectrum of early development and registrational/pivotal Phase 1-4 clinical trials, leading to successful regulatory filings and new product launches worldwide. He received an MD and a Doctorate degree in Pharmacology from the Medical School, University of Athens, Athens, Greece, and a PhD in Psychiatry/Neuroscience from theUniversity of British Columbia, Vancouver, BC, Canada. He is licensed to practice medicine inGreece and Sweden and was an Associate Professor of Pharmacology at Karolinska Institutet, Stockholm, Sweden. Dr Nomikos has published more than 180 peer-reviewed articles and reviews, authored several book chapters and patents, and edited a textbook on Translational Medicine in CNS Drug Development.

Spyros Papapetropoulos M.D. Ph.D. has been a member of Lipocine's board since April 2022. He is an experienced biopharmaceutical executive, recognized neuroscientist, neurodegenerative disease clinician and change agent. He is currently Chief Medical Officer at Vigil Neuro. Previously he served as Chief Development Officer, and SVP, Head of Development at Acadia Pharmaceuticals Inc., CEO at SwanBio Therapeutics, and Head of Research & Development and Chief Medical Officer at Cavion. Before Cavion, he held senior/executive positions at Biogen Inc., Allergan plc, Pfizer Inc., and Teva Pharmaceuticals Inc. Over the last 25 years Spyros has overseen a broad spectrum of CNS-focused academic and biopharmaceutical R&D programs (small molecules, biologics, gene therapy) leading to successful regulatory filings and new product launches worldwide. He trained as a Movement Disorders Neurologist at the National Hospital for Neurology and Neurosurgery in London, UK and was faculty at the University ofMiami, School of Medicine prior to joining the biopharmaceutical industry. Spyros has authored more than 170 peer-reviewed publications with ~8K citations, several patents, book chapters, presented and chaired meetings since 1997. He received his MD and PhD from University of Patras, School of Health Sciences, Faculty of Medicine (Greece).

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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For further information: Krista Fogarty, Phone: (801) 994-7383, kf@lipocine.com; Investors: Hans Vitzthum, Phone: (617) 430-7875, hans@lifesciadvisors.com

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