August 31, 2026

Ensysce Biosciences Completes Final Phase of PF614-MPAR-102 Clinical Study

~ ~ The Second Study Fully Enrolled for Breakthrough Therapy-Designated, First-in-Class Opioid Designed to Protect Against Oral Overdose ~ ~

SAN DIEGO, CA / ACCESS Newswire / August 31, 2026 / Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or the "Company"), a biotechnology company developing novel neuroplastogenic therapies beyond mood disorders, with an initial focus on complex pain, and advancing next-generation pain and central nervous system therapeutics designed to reduce abuse and overdose risk, today announced completion of enrollment in the final stage of the PF614-MPAR-102 clinical study. The study evaluated its novel MPAR® (Multi-Pill Abuse Resistance) overdose-protection technology.

Unlike traditional abuse-deterrent technologies, PF614-MPAR is engineered to actively protect against oral overdose, addressing one of the most persistent risks in opioid therapy. Its proprietary chemical-control mechanism provides therapeutic opioid exposure when used as prescribed and automatically limits additional release when excessive doses are taken. This built-in "safety switch" establishes a new therapeutic paradigm: opioids designed not only for efficacy, but also for controlled exposure under misuse conditions.

Part 3 of this second PF614-MPAR study, supported by the National Institute on Drug Abuse (NIDA)[1], was designed to further characterize the drug's protective profile against a full range of dosing scenarios. Clinical data published to date demonstrates PF614-MPAR maintains consistent therapeutic plasma levels at normal doses while significantly blunting exposure increases at supratherapeutic levels.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, stated, "Completing enrollment in this second PF614-MPAR study marks an important milestone for Ensysce as we advance a Breakthrough Therapy-designated program targeting one of the most urgent challenges in prescription opioid therapy: overdose risk. PF614-MPAR is designed to deliver therapeutic opioid exposure when used as prescribed while limiting additional release at excessive doses, a differentiated approach we believe could redefine prescription opioid safety. With nearly 80,000 people in the U.S. still dying each year from opioid overdose, prescription opioids remain a significant part of this crisis[2]. By embedding overdose protection directly into the molecule, MPAR® represents a potentially new class of chemically engineered opioids and an important step toward a safer standard of care for pain management."

Beyond pain management, Ensysce is leveraging its TAAP and MPAR® technologies to expand its pipeline across additional high-need therapeutic categories. The Company has identified lead TAAP analogues for amphetamine and methadone, supporting a broader strategy to develop safer treatment options for pain, attention-deficit/hyperactivity disorder (ADHD), and opioid use disorder, in addition to its newly acquired psychedelic program for

Complex Regional Pain Syndrome.

[1]Research supporting this program was funded by the National Institute on Drug Abuse of the National Institutes of Health under Award Number DA047682.

[2]https://drugabusestatistics.org/opioid-epidemic/

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage biotechnology company developing novel neuroplastogenic therapies using psychedelics that go beyond mood disorders and address the root cause of chronic pain through central nervous system modulation. The company is also developing a new class of highly novel opioids for the treatment of severe pain while minimizing the risk of both drug abuse and overdose. For more information, please visit www.ensysce.com.

Forward-Looking Statements

Statements contained in this press release that are not purely historical may be deemed to be forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. Without limiting the foregoing, the use of words such as "may," "intends," "can," "might," "will," "expect," "plan," "possible," "believe" and other similar expressions are intended to identify forward-looking statements. The product candidates discussed are in clinic and not approved and there can be no assurance that the clinical programs will be successful in demonstrating safety and/or efficacy, that Ensysce will not encounter problems or delays in clinical development, or that any product candidate will ever receive regulatory approval or be successfully commercialized. All forward-looking statements are based on estimates and assumptions by Ensysce's management that, although Ensysce believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Ensysce expected. In addition, Ensysce's business is subject to additional risks and uncertainties, including among others, possible NASDAQ delisting, the initiation and conduct of preclinical studies and clinical trials; the timing and availability of data from preclinical studies and clinical trials; expectations for regulatory submissions and approvals; potential safety concerns related to, or efficacy of, Ensysce's product candidates; the availability or commercial potential of product candidates; continuation of government funding; the ability of Ensysce to fund its continued operations, including its planned clinical trials; the dilutive effect of stock issuances from our fundraising; and Ensysce's and its partners' ability to perform under their license, collaboration and manufacturing arrangements. These statements are also subject to a number of material risks and uncertainties that are described in Ensysce's most recent quarterly report on Form 10-Q and current reports on Form 8-K, available free of charge at the SEC's website at www.sec.gov. Any forward-looking statement speaks only as of the date on which it was made. Ensysce undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required under applicable law.

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SOURCE: Ensysce Biosciences

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