

Ensysce Biosciences Receives U.S. Patent for Groundbreaking Treatment of Opioid Use Disorder

- ~ Applies TAAP and MPAR Technology to Produce Novel OUD Treatments ~
- ~ Prioritizes Safety and Tolerability for OUD Patients ~

SAN DIEGO, CA / ACCESS Newswire / April 23, 2025 / Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or the "Company"), a clinical-stage pharmaceutical company developing innovative solutions for severe pain relief while reducing the potential for abuse and overdose, today announced it received a Notice of Allowance from the U.S. Patent and Trademark Office for the issuance of a patent entitled: Enzyme-Cleavable Methadone Prodrugs and Methods of Use Thereof¹ including both composition of matter and method of use claims. PF9001, the innovative medication covered by this patent, is designed to provide a safer treatment option for opioid use disorder (OUD) by using Ensysce's TAAPTM and MPAR[®] abuse deterrent and overdose protection technologies.

Methadone has long been a cornerstone treatment for OUD, but its use has been limited by concerns over cardiac side effects, respiratory depression, and risk of overdose. Ensysce has developed a new class of agents for the treatment for OUD in the form of PF9001. This new drug is a significant advancement in the treatment of OUD, with data demonstrating a reduction in potential for cardiotoxicity, validating MPAR[®] overdose protection, and indications of potentially delivering a prolonged and predictable effect following once daily dosing.

Dr. Richard Dart, Director of the Rocky Mountain Poison and Drug Center who specializes in emergency medicine and toxicology commented, "Novel agents for the treatment of OUD are needed. The MPAR technology applied to methadone analogues has the potential to save lives by reducing overdose."

Dr. Lynn Kirkpatrick, CEO of Ensysce, added, "PF9001 and this approach is the result of years of dedicated research focused on providing safer medications for the treatment of OUD while reducing the risks associated with its therapy. Our novel TAAP and MPAR technology offers patients and providers a safer, more tolerable alternative to current therapy which has been recognized with financial support provided by the National Institute on Drug Abuse. We believe PF9001 could potentially increase treatment adherence and improve outcomes for OUD patients."

¹The research covered by this patent was supported by the National Institute on Drug Abuse of the National Institutes of Health under Award Number UG3DA050271.

About Ensysce Biosciences

Ensysce Biosciences is a clinical stage company with a goal of disrupting the analgesic landscape by introducing a new class of highly novel opioids for the treatment of severe pain. Leveraging its Trypsin-Activated Abuse Protection (TAAPTM) and Multi-Pill Abuse Resistance (MPAR[®]) platforms, the Company is developing unique, tamper-proof treatment options for pain that minimize the risk of both drug abuse and overdose. Ensysce's products are anticipated to provide safer options to treat patients suffering from severe pain and assist in preventing deaths caused by medication abuse. 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, 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; 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-K and current reports on Form 8-K, which are 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.

Ensysce Biosciences Company Contact:

Lynn Kirkpatrick, Ph.D. Chief Executive Officer (858) 263-4196

Ensysce Biosciences Investor Relations Contact:

Shannon Devine MZ North America Main: 203-741-8811

ENSC@mzgroup.us

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