July 23, 2024

Ensysce Biosciences Provides Mid-Year 2024 Update

~ Ready to Commence PF614 Phase 3 Clinical Trial in 2024 ~

~ Continued Clinical Development of Overdose Protection Breakthrough Therapy ~

~ Identified Lead Clinical Candidate for Opioid Use Disorder Program ~

SAN DIEGO, CA / ACCESSWIRE / July 23, 2024/ 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 opioid abuse and overdose, today provides a Company review and update on a successful first half of 2024, including achievement of Breakthrough Therapy designation from the U.S. Food & Drug Administration (FDA).

Recent clinical and development highlights:

PF614:

- Successfully completed a PF614 End of Phase 2 meeting with the FDA, which provided guidance on strategy and design of the Phase 3 clinical program.
- Published the results of clinical study P614-102, which determined that PF614 was bioequivalent to OxyContin, potentially allowing it to be developed through the shortened FDA 505(b)(2) regulatory pathway. The results were published in an article entitled ‘Clinical evaluation of PF614, a novel TAAPä prodrug of oxycodone, versus OxyContin® in a multi-ascending dose study with a bioequivalence arm in healthy volunteers'.
- Established manufacturing partnerships with Societal CDMO, Porton Pharma Solutions, and Purisys LLC to position Ensysce for commercial scale production of PF614.

PF614-MPAR:

- The FDA granted Breakthrough Therapy designation to PF614-MPAR, specifically acknowledging the potential impact of the innovative MPAR® overdose protection technology. Breakthrough Therapy is an elite designation that expedites the development and review of drugs that are intended to treat a serious condition where the drug may demonstrate substantial improvement over available therapies.
- Applied for an additional $15 million non-dilutive grant funding from National Institutes of Health (NIH) and National Institute on Drug Abuse (NIDA) to support three years of

continued development for PF614-MPAR with a potential start date in the third quarter of 2024.

- Presented the clinical data for PF614-MPAR that resulted in the granting of Breakthrough Therapy designation at the NIH annual HEAL (Helping End Addiction Long term) meeting, and the PF614-MPAR platform was recognized in the Trailblazer Session presented at the 2024 American Association of Pain Medicine (AAPM) annual meeting.

- Received guidance from the FDA for the efficient execution of the non-clinical program, potentially reducing required costs.

- Advanced the PF614-MPAR program in a continued collaboration with Quotient Sciences to undertake a second clinical trial, PF614-MPAR-102, anticipated to start in the fourth quarter of 2024.

Opioid Use Disorder (OUD) program:

- Achieved a major milestone in the Company's opioid use disorder (OUD) program with selection of a lead drug candidate. The lead candidate PF9001, a TAAP methadone analogue, has shown lower potential of cardiovascular side effects associated with traditional methadone treatment.

- The OUD program is supported by non-dilutive grant funding through the Company's ongoing $15 million multi-year NIDA HEAL award.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "Our team has made exceptional progress on all three of the company's discovery and development programs during the first half of 2024. We continued to make positive traction in successful meetings with the FDA relative to both the PF614 and PF614-MPAR programs. The PF614 Phase 3 protocol is currently being finalized and we look forward to initiating enrollment in the study later this year. We also are pleased to be working with Quotient Sciences to develop our second clinical protocol for PF614-MPAR. Following completion of the PF614-MPAR-102 trial, we anticipate another meeting with the FDA to discuss the clinical path of PF614-MPAR. Finally, we are continuing the non-clinical development of our OUD program and are exploring other opportunities for our TAAP/MPAR analogues for ADHD."

"Safety of opioids and access to pain care remain huge issues in the US. We remain optimistic on our path to commercialization of our drugs to help solve these two problems. Our TAAP platform is designed to reduce abuse and the inclusion of MPAR will create far safer therapeutic products to protect from oral overdose. In addition to our traditional means of financing, Ensysce consistently applies for non-dilutive federal government funding to support our groundbreaking work, with the goal of providing effective pain relief for those suffering with severe pain. We look forward to providing additional updates in the months ahead and appreciate the support of our industry partners to achieve our goals and the continued support of our dedicated shareholders," concluded Dr. Kirkpatrick.

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage company using its proprietary technology platforms

to develop safer prescription drugs. Leveraging its Trypsin-Activated Abuse Protection (TAAP™) 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. The platforms are covered by an extensive worldwide intellectual property portfolio for a wide array of prescription drug compositions. For more information, please visit www.ensysce.com.

Definitions

TAAP: trypsin activated abuse protection - designed to protect against prescription drug abuse.

MPAR: multi-pill abuse resistance - designed to protect against abuse and accidental overdose.

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-Q 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.

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