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Ensysce Biosciences Provides Shareholder Update, Responds to Recent Shareholder Inquiries

SAN DIEGO, CA / ACCESSWIRE / October 2, 2024 /Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or "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 response from Chief Executive Officer, Dr. Lynn Kirkpatrick, regarding recent inquiries from stockholders and other interested parties.

Dear Fellow Stockholders,

It is important to me to directly deliver an update to our supportive shareholders, stakeholders and partners, by addressing some questions we have recently received and providing a concise view of our development progress and timelines.

What is the latest update from the Company in terms of Nasdaq listing requirements?

As of September 30, 2024, we believe we are in compliance with Nasdaq requirements regarding stockholders' equity and we are looking forward to the upcoming hearing with Nasdaq to discuss our plans to continue to maintain compliance with both the stockholders' equity requirement and the $1.00 bid price requirement.

How much cash does Ensysce have to continue to make progress on its initiatives?

In August, the Company completed a financing transaction which raised $5 million in gross proceeds and received a $14 million multi-year grant award from the NIH.

What are the latest plans and timeline of the PF614-301 protocol of the study, "A Multicenter, Randomized, Double-Blind, Placebo-and Active-Controlled Study to Evaluate the Efficacy and Safety of PF614 for the Treatment of Moderate to Severe Pain after Abdominoplasty"?

We submitted our PF614-301 Phase 3 Protocol to the FDA for our pivotal Phase 3 study, as announced on September 19, 2024. This study is designed to assess the analgesic efficacy of PF614 compared to placebo in subjects with moderate-to-severe pain following abdominoplasty. Results from the study are expected in late 2025.

Next Steps: We await feedback on the protocol from the FDA. A Clinical Advisory Board meeting is planned for early November in which we will review the feedback and incorporate any advice into our study plans. Steps are being taken to identify clinical sites, and study management proposals have been solicited and received from interested Contract Research Organizations.

Following receipt of grant funding for development of PF614-MPAR, will you provide the progress of the current clinical trial and frame out the remainder of trials to FDA approval?

With $14 million of non-dilutive funding through a multi-year grant from the NIH and National Institute on Drug Abuse received for the purpose of continuing our PF614-MPAR studies, we have initiated a number of non-clinical studies required to support our PF614-MPAR NDA (New Drug Application). In addition, we have received Investigational Review Board approval of the PF614-MPAR-102 protocol and held a kickoff meeting to prepare for subject enrollment, anticipated to begin later this quarter.

What additional components are required in terms of achieving FDA approval and commercialization of PF614?

Besides completing the necessary Phase 3 clinical studies to gain FDA approval, outlined above, Ensysce has partnerships in place with both drug substance and drug product contract development and manufacturing organizations to scale our manufacturing needs for production of clinical trial material, registrational material and commercial material for our first drug launch. In addition, we have received proposals from packaging and labeling facilities, and we are finalizing the steps needed to have commercial product in place to be shipped as soon as we receive approval from the FDA.

Subject to raising additional funds, which cannot be assured, we are on track to submit our PF614 New Drug Application by 2026 and commercialization to follow by end of that year.

Is ENSC evaluating strategic partnerships or indications of interest in terms of funding a safer opioid option and expedite commercialization?

Ensysce has been in discussions with several interested partners to expand the commercial success of PF614 and PF614-MPAR. We are committed to leveraging cash and non-cash resources to reach our objectives.

What action do you have in place to enhance shareholders' value?

We have been executing our clinical and development strategy with positive results over the last several years. We continue to make progress in all of our programs, including Breakthrough Therapy designation from the FDA and the successful completion of a bioequivalence clinical study for our oral overdose protected opioid, PF614-MPAR. We have also successfully completed two Human Abuse Potential studies for PF614. We continue to forge forward despite the outside pressure of a difficult macro environment for microcap companies.

If you have additional questions that were not answered today, please submit them to ENSC@mzgroup.us.

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.

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 its 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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