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Ensysce Biosciences Advances CRPS Program at Painweek 2026, Contributes to FDA Hearing on Psychedelic Drug Regulation

SAN DIEGO, CA / ACCESS Newswire / September 15, 2026 / Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or the "Company") a clinical-stage biotechnology company developing novel neuroplastogenic therapies beyond mood disorders, with an initial focus on CRPS (Complex Regional Pain Syndrome), hosted a symposium at PainWeek 2026. The Symposium was attended by more than 320 pain management professionals. Dr. Jeff Gudin provided background on the Ensysce novel program to provide safer opioids for severe pain as well as a substantial background on complex pain, specifically Complex Regional Pain Syndrome Type 1 (CRPS). Dr. Richard Langford also outlined the novel approach to CRPS, the platform that Ensysce recently added to its toolbox through the acquisition of Cy Biopharma.

Following PainWeek, a team from Ensysce was invited to attend the FDA hearing in to obtain feedback and perspectives on regulatory, training, credentialing of professionals associated with the therapeutic use of psychedelic drugs, patient safety and real-world data collection. Dr. Langford provided comments during the session discussing ‘Considerations for access; Best practices for data collection and standardization'. The public comments safety of psychedelic drugs, the training and credentialing of therapists, psychiatrist and the regulatory requirements for access to the subjects with mental health issues or pain-based indications. Dr. Langford specifically addressed the access and use of interventional Pain Physicians for the delivery of psychedelic drugs.

"The FDA's hearing provided a substantial voice to the public for the FDA's understanding of psychedelic-based medicines, their use, access and the training of individuals involved with the treatment," said Lynn Kirkpatrick, Ph.D., Chief Executive Officer of Ensysce Biosciences. "We are eager to advance these novel neuroplastogenic therapies and the implementation of our Phase 2 clinical trial. Being able to hear the comments from nurses, pharmacists, therapists, physicians and patients themselves from the United States, Canada and Mexico, as well as the outcomes from various states that have established clinical psychedelic programs put this highly promising therapeutic care into a public perspective."

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," "might," "will," "expect," "plan," "possible," "believe" and other similar expressions are intended to identify forward-looking statements. All forward-looking statements are based upon management's estimates and forecasts and reflect the current views, assumptions, expectations and opinions of the Company as of the date hereof. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those expected, including (i) possible Nasdaq delisting; (ii) failure to obtain stockholder approval for the conversion of the Series C non-voting convertible preferred stock into shares of common stock of the combined company; (iii) risks related to the combined company's ability to manage its operating expenses and its expenses associated with the acquisition; (iv) unexpected costs, charges or expenses resulting from the acquisition; (v) potential adverse reactions or changes to business relationships resulting from the announcement or completion of the acquisition; (vi) the uncertainties associated with the combined company's product candidates, as well as risks associated with the clinical development and regulatory approval of product candidates, including potential delays in the commencement and completion of clinical trials, studies and evaluations; (vii) risks related to the inability of the combined company to obtain sufficient additional capital, including the continuation of government funding, to continue to advance these or other product candidates; (viii) failure to achieve the clinical trial milestone for the Milestone Closing; (ix) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (x) risks related to the failure to realize any value from product candidates currently being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; and (xi) risks associated with the possible failure to realize certain anticipated benefits of the acquisition, including with respect to future financial and operating results. These statements are also subject to risks and uncertainties described in Ensysce's most recent annual report on Form 10-K and quarterly report on Form 10-Q and in other filings that it makes with the U.S. Securities and Exchange Commission (the "SEC"), available 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, except as required under applicable law.

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