## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549** 

## FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 8, 2021 (July 8, 2021)

## **Ensysce Biosciences, Inc.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

001-38306 (Commission File Number)

82-2757287 (I.R.S. Employer Identification Number)

7946 Ivanhoe Avenue, Suite 201 La Jolla, California (Address of principal executive offices)

92037 (Zip Code)

(858) 263-4196 Registrant's telephone number, including area code

N/A

(Former name	e or former address, if changed since last	report)
Check the appropriate box below if the Form 8-K filing is intended to	simultaneously satisfy the filing obligation	to the registrant under any of the following provisions:
☐ Written communications pursuant to Rule 425 under the Securitie	s Act (17 CFR 230.425)	
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange A	act (17 CFR 240.14a-12)	
☐ Pre-commencement communications pursuant to Rule 14d-2(b) us	nder the Exchange Act (17 CFR 240.14d-2	(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) un	nder the Exchange Act (17 CFR 240.13e-4(	c))
Securities registered pursuant to Section 12(b) of the Act:		
Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share Warrants to purchase one share of Common Stock	ENSC ENSCW	The Nasdaq Stock Market LLC The Nasdaq Stock Market LLC
Emerging growth company ⊠		
If an emerging growth company, indicate by check mark if the registr accounting standards provided pursuant to Section 13(a) of the Exchar		nsition period for complying with any new or revised financial

### Item 7.01. Regulation FD Disclosure.

On July 8, 2021, Ensysce Biosciences, Inc. (formerly known as Leisure Acquisition Corp.), a Delaware corporation (the "Company") issued a press release announcing the receipt of a Notice of Award from the National Institute on Drug Abuse. The press release is attached as Exhibit 99.1 and incorporated by reference herein.

The information in this Item 7.01, including Exhibit 99.1, is furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to liabilities under that section, and shall not be deemed to be incorporated by reference into the filings of the Company under the Securities Act or the Exchange Act, regardless of any general incorporation language in such filings. This report will not be deemed an admission as to the materiality of any of the information contained in this Item 7.01, including Exhibit 99.1.

This report contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1934, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements may be made directly in this report. Some of the forward-looking statements can be identified by the use of forward-looking words. Statements that are not historical in nature, including the words "anticipate," "expect," "suggests," "plan," "believe," "intend," "estimates," "targets," "projects," "should," "would," "may," "will," "forecast" and other similar expressions are intended to identify forward-looking statements. All forward-looking statements are based upon management estimates and forecasts and reflect the views, assumptions, expectations, and opinions of the Company as of the date of this report, and may include, assumptions, expectations, forecasts, views or opinions set forth in this report constitute the Company's judgments and should be regarded as indicative, preliminary and for illustrative purposes only. The forward-looking statements and projections contained in this report are subject to a number of factors, risks and uncertainties, some of which are not currently known to the Company, that may cause the Company's actual results, performance or financial condition to be materially different from the expectations of future results, performance of financial condition. Although such forward-looking statements have been made in good faith and are based on assumptions that the Company believes to be reasonable, there is no assurance that the expected results will be achieved. The Company's actual results may differ materially from the results discussed in forward-looking statements. Additional information on factors that may cause actual results and the Company's performance to differ materially is included in the Company's methal performance to differ materially from the results discussed in forward-looking statements. Additional information on factors that may cause actual result

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number Description

99.1 Press Release, dated as of July 8, 2021.

#### **SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: July 8, 2021 Ensysce Biosciences, Inc.

By: /s/ Lynn Kirkpatrick
Name: Dr. Lynn Kirkpatrick

Title: President and Chief Executive Officer

# Ensysce Biosciences Receives Notice of Award for Year Three of Multi-Year NIDA Grant for the Clinical Development of its Next Generation Opioid Products with Overdose Protection

Company's Proprietary TAAP Prodrug Delivery and Overdose Technology Aims to Stem The Opioid Abuse Epidemic

San Diego, CA — July 8, 2021 Ensysce Biosciences, Inc. (NASDAQ: ENSC) ("Ensysce" or "the Company"), a clinical stage biotech company with proprietary technology platforms to reduce the economic and social burden of prescription drug abuse and overdose, today announced receipt of the 3<sup>rd</sup> year award of a multi-year grant from the National Institute on Drug Abuse (NIDA). This award will provide \$2.8 million to initiate a Phase 1 study of the first MPAR<sup>TM</sup> overdose protection product in the U.S., PF614-MPAR. This brings the total support of NIDA to \$8.0 million. An additional \$2.8 million award for year four is pending.

"We are honored to receive the UH3 award titled "PF614 MPAR Abuse Deterrent opioid prodrug with overdose protection: Pre-Clinical Development and Phase 1 Clinical Trial" from the National Institute on Drug Abuse, which provides us with additional resources to continue our work to bring PF614-MPAR™ into clinical development," said Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce Biosciences. "Importantly, our next-generation opioid platform is highly differentiated from currently marketed opioid products and designed to significantly reduce abuse potential and overdose protection. We remain focused on our commitment to stem the prescription drug abuse epidemic and look forward to bringing our unique pipeline of products to the industry, which will ultimately provide safer options for both prescribers and patients."

PF614-MPAR<sup>TM</sup> is designed as an extended-release oxycodone prodrug with both trypsin-activated abuse protection (TAAP) and overdose protection through multi-pill abuse resistance (MPAR<sup>TM</sup>) technology. TAAP chemical modification inactivates the active ingredient in PF614 to provide abuse deterrence, and the combination with the trypsin inhibitor, nafamostat, in MPAR<sup>TM</sup> provides the additional layer of overdose protection. The MPAR<sup>TM</sup> overdose protection has been demonstrated in animals and the Phase 1 study with PF614 is being conducted to further validate the MPAR<sup>TM</sup> overdose protection technology. The Phase 1 study trial, "A Single Dose Study to Evaluate the Pharmacokinetics of oxycodone and PF614, when PF614 Solution is Co-Administered with Nafamostat, as an Immediate Release Solution and/or Extended Release (ER) Capsule Formulations in Healthy Subjects" is being conducted by Dr. Maricer Escalon MD, MS, MBA at Quotient Sciences.

"This award further confirms Ensysce's important TAAP and MPAR™ technology, which has been recognized by NIH, NIDA and the Federal Government," said Dr. William Schmidt, Chief Medical Officer of Ensysce. "We remain committed to addressing the significant unmet needs in the marketplace, and look forward to advancing our pipeline of opioid TAAP and MPAR™ products to combat the opioid crisis."

### **About Ensysce Biosciences:**

Ensysce Biosciences, San Diego, CA is a clinical-stage biotech company using its proprietary technology platforms to develop safer prescription drugs. Leveraging its Trypsin Activated Abuse Protection (TAAP) and Multi-Pill Abuse Resistance (MPAR<sup>TM</sup>) platforms, the Company is in the process of developing a new class of powerful, tamper-proof opioids that prevent both drug abuse and overdoses. Ensysce's products are anticipated to provide safer options to treat severe pain and assist in preventing deaths caused by opioid abuse, reducing the human and economic cost. The platforms are covered by an extensive worldwide intellectual property portfolio for a wide array of prescription drug compositions. For more information, please visit <a href="https://www.ensysce.com">www.ensysce.com</a>.

### 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," 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; 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 definitive proxy statement/prospectus relating to the recently completed business combination with Leisure Ac

### **Ensysce Biosciences Company Contact**

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