# 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): November 16, 2021 (November 15, 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) 82-2755287 (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 of	r former address, if changed since la	ast report)
Check the appropriate box below if the Form 8-K filing is intended to sin	nultaneously satisfy the filing obligation	on to the registrant under any of the following provisions:
$\Box$ Written communications pursuant to Rule 425 under the Securities A	Act (17 CFR 230.425)	
$\hfill \Box$ Soliciting material pursuant to Rule 14a-12 under the Exchange Act	(17 CFR 240.14a-12)	
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under	er the Exchange Act (17 CFR 240.14d	l-2(b))
$\ \square$ Pre-commencement communications pursuant to Rule 13e-4(c) under	er 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 registrant accounting standards provided pursuant to Section 13(a) of the Exchange		transition period for complying with any new or revised financial

#### Item 2.02. Results of Operations and Financial Condition.

On November 15, 2021, Ensysce Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 30, 2021. A copy of the press release is included as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor will they be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, except as will be expressly set forth by specific reference in such a filing.

#### Forward-Looking Statements

This report contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, 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," "could," "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, without limitation, changes in general economic conditions, including as a result of COVID-19, all of which are accordingly subject to change. Any such estimates,

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 filings with the Securities and Exchange Commission (the "SEC") (including filings as Leisure Acquisition Corp.). Copies of such filings with the SEC are available publicly on the SEC's website at <a href="www.sec.gov">www.sec.gov</a> or may be obtained by contacting the Company. Readers are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made. These forward-looking statements are made only as of the date hereof, and the Company does not undertake any obligations to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated November 15, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

#### **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: November 16, 2021 Ensysce Biosciences, Inc.

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

Title: President and Chief Executive Officer (Principal Executive Officer)

#### Ensysce Biosciences Reports Third Quarter 2021 Financial Results and Recent Corporate Updates

SAN DIEGO, Nov. 15, 2021 — Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ: ENSC, OTC: ENSCW), a clinical-stage biotech company with proprietary technology platforms to reduce the economic and social burden of prescription drug abuse and overdose, today reported financial results for the third quarter of 2021 and recent corporate updates.

"In the third quarter, we successfully completed our convertible note financing of \$15 million that provided us with the necessary proceeds to continue our advancement of our lead clinical trial programs," said Dr. Lynn Kirkpatrick, CEO of Ensysce. "As previously announced, we commenced our second study of our TAAP opioid, PF614, in early September, and through this study, we aim to demonstrate the correlation between PF614 to Oxycontin, and how Ensysce can begin to make this solution readily available for public use. Additionally, we appointed Dr. Linda Pestano as our Chief Development Officer. Linda's extensive expertise in the preclinical drug development area makes her a perfect addition to our team as we work towards commercializing our next-generation opioid products."

Dr. Kirkpatrick concluded, "We're continuing to develop the next generation of innovative solutions to combat the potential for opioid abuse, and we're pleased with our progress to date. We believe we have the necessary resources and bandwidth to continue to progress on our important mission."

#### **Program Updates**

#### TAAP - opioid abuse deterrent program:

- On September 7, 2021, Ensysce enrolled the first cohort of subjects in a clinical study PF614-102 entitled "A Phase 1b, Randomized, 2-Part Single-Center Study to
  Evaluate the Pharmacokinetics and Safety of Multiple-Ascending Oral Doses of PF614 and the Food Effect and Bioavailability/Bioequivalence of Single Oral Doses of
  PF614 Relative to OxyContin in Healthy Adult Subjects."
- This study builds on the results of the initial Phase 1 study and is designed to help us understand how PF614 compares to currently available commercial products.

#### Other Business Highlights

- Ensysce completed a \$15 million convertible note financing, receiving the second tranche of \$10 million on November 5, 2021 after receiving the first tranche of \$5 million on September 24, 2021.
- Total gross proceeds from the convertible note financing will be used for general working capital purposes, allowing for advancement of lead clinical trial programs including the completion of the PF614-102 bioequivalence study, as well as continuing the clinical development of the overdose protection platform with our lead product PF614-MPAR.

#### Third Quarter 2021 Financial Results

- Cash Cash and cash equivalents were \$6.8 million as of September 30, 2021. On November 5, 2021, Ensyste received additional funding of \$10 million under the convertible note financing.
- Federal Grants Funding under federal grants was \$1.2 million for the third quarter of 2021 compared to \$0.8 million for the third quarter of 2020. The increase is attributable to increased clinical development activity with our PF614-MPAR overdose protection product.
- R&D Expenses Research and development expenses were \$1.7 million for the third quarter of 2021 compared to \$0.9 million for the same period in 2020. The increase primarily resulted from increased clinical development activity with our PF614 abuse protection product and combination product PF614-MPAR for overdose protection.
- **G&A Expenses** General and administrative expenses were \$16.4 million for the third quarter of 2021 compared to \$0.3 million for the third quarter of 2020. The increase was primarily a result of \$11.6 million of non-cash expenses for warrants issued under a December 2020 share subscription facility following the Company's listing on Nasdaq in July 2021 and \$2.3 million of non-cash expenses related to equity for consultants.
- Net Loss Net loss for the third quarter of 2021 was \$17.2 million compared to net income of \$1.6 million for the same period in 2020.

#### About Ensysce Biosciences (NASDAQ: ENSC)

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 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

This press release contains certain forward-looking statements within the meaning of federal securities laws. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this communication. Such factors can be found 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 <a href="https://www.sec.gov">www.sec.gov</a>. New risks and uncertainties arise from time to time, and it is impossible for us to predict these events or how they may affect the Company. You are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made, and Ensysce undertakes no obligation to update or revise the forward-looking statements, whether as a result of new information, changes in expectations, future events or otherwise.

#### **Investor Relations Contact:**

Gateway Investor Relations Matt Glover, Alex Thompson (949) 574-3860 Ensysce@gatewayir.com

# Ensysce Biosciences, Inc. Unaudited Condensed Consolidated Statements of Operations

	 Three Months Ended September 30,			Nine Months Ended September 30,			
	 2021		2020		2021		2020
Federal grants	\$ 1,200,816	\$	827,639	\$	1,895,907	\$	3,514,720
Operating expenses:							
Research and development	1,714,635		892,991		2,502,232		3,136,207
General and administrative	16,372,976		339,422		17,257,361		898,470
Total operating expenses	 18,087,611		1,232,413		19,759,593		4,034,677
Loss from operations	(16,886,795)		(404,774)		(17,863,686)		(519,957)
Total other income (expense), net	 (312,679)		1,955,280		(1,245,091)		340,742
Net income (loss)	\$ (17,199,474)	\$	1,550,506	\$	(19,108,777)	\$	(179,215)

## Ensysce Biosciences, Inc. Unaudited Condensed Consolidated Balance Sheets

	September 30, 2021		December 31, 2020		
Assets					
Current assets:					
Cash and cash equivalents	\$	6,845,672	\$	194,214	
Prepaid expenses and other current assets		2,075,636		153,662	
Total current assets		8,921,308		347,876	
Other assets		796,423		3,931	
Total assets	\$	9,717,731	\$	351,807	
Liabilities and stockholders' deficit Current liabilities:					
Accounts payable	S	471,858	\$	1,724,598	
Accrued expenses and other liabilities	Ψ	3,762,429	Ψ	370,292	
Notes payable and accrued interest		2,797,181		4,245,082	
Embedded derivative on convertible notes				670,262	
Total current liabilities		7,031,468		7,010,234	
Long-term liabilities		3,071,550		_	
Total liabilities		10,103,018		7,010,234	
Stockholders' deficit		(385,287)		(6,658,427)	
Total liabilities and stockholders' deficit	\$	9,717,731	\$	351,807	