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): May 13, 2025 (May 13, 2025)

Ensysce Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38306**	**82-2755287**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(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 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 Securities Act (17 CFR 230.425)

☐ 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 the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under 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	**ENSC**	**The Nasdaq Stock Market LLC**

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On May 13, 2025, Ensysce Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended March 31, 2025. 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 and political conditions, 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"). Copies of such filings with the SEC are available publicly on the SEC's website at www.sec.gov 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 May 13, 2025
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: May 13, 2025

Ensysce Biosciences, Inc.

By: */s/ Lynn Kirkpatrick*
Name: Dr. Lynn Kirkpatrick
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 99.1

Ensysce Biosciences Reports First Quarter 2025 Financial Results

Receives U.S. Patent for Groundbreaking Treatment for Opioid Use Disorder

Clinical Trial on Novel Analgesic, PF614-MPAR, Demonstrates Overdose Protection

SAN DIEGO, CA / May 13, 2025 / 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 reported financial and operational results for the first quarter ended March 31, 2025.

Dr Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "We are pleased with the meaningful strides the Company has continued to make in the first quarter to deliver what we believe are the 'Next Generation' opioid analgesics with both abuse and overdose protection. Included in our recent accomplishments was the receipt of a Notice of Allowance from the U.S. Patent and Trademark Office for our lead opioid use disorder (OUD) drug candidate, PF9001. This patent adds to our portfolio of over 100 patents that span 25 countries around the world for our TAAP and MPAR® technologies in the pain and attention deficit disorder space. PF9001 is designed to have several advantages over current methadone therapy including overdose protection from our MPAR technology and reduced cardiotoxicity, which is a serious side effect seen with medications used today. We believe our approach to OUD therapy utilizing our novel TAAP and MPAR technologies will improve outcomes for patients through an increase in treatment adherence as well as provide much easier access to these critical therapies for those who struggle with this disorder."

Dr. Kirkpatrick continued, "Additionally in April, we were pleased to announce completion of another critical milestone in the development of our opioid overdose protection. Part 1 of our PF614-MPAR-102 clinical study finished enrollment and confirmed protection from the risk of overdose when PF614-MPAR at any dose level is consumed accidentally or deliberately. We look forward to enrolling Parts 2 and 3 of the study which will continue to examine other properties of PF614-MPAR to support its use to treat severe pain when other analgesics are ineffective."

"We believe Ensysce is set to disrupt the analgesic opioid market with our lead products PF614 and PF614-MPAR. Our mission has been to use "clever chemistry" to deliver a novel opioid analgesic featuring both abuse and overdose protection while retaining opioid-grade efficacy. As we approach the second half of the year, we have set in place plans for clinical and regulatory progress and look forward to continuing to provide updates on our TAAP, MPAR and OUD programs. The opioid crisis continues to claim close to 100,000 lives annually in the U.S. alone. Ensysce aims to not only save lives, but to reshape the way society approaches pain and addiction."

TAAP™ (Opioid Abuse Deterrent Program) Update

The Company's lead product, PF614, is a Trypsin-Activated Abuse Protection (TAAP™) extended-release oxycodone and a potential "next generation" analgesic to treat severe pain. PF614's TAAP™ chemical modification of oxycodone makes it inactive until it is swallowed and exposed to the body's own trypsin in the small intestine to activate or "switch on" to release oxycodone. The TAAP™ technology is designed to control release when administered orally, be highly resistant to tampering, and reduce abuse, with a goal of providing what the Company believes is a safer opioid product for those suffering with severe pain who require opioid-strength analgesia.

Having received FDA feedback on the Phase 3 design for the PF614-301 clinical study, entitled "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", in December 2024, the Company has continued to perfect its study plans, working towards initiating the trial in mid-year 2025, and will continue to provide updates as the program develops.

MPAR® (Opioid Abuse Deterrent and Overdose Protection Program) Update

PF614-MPAR is a combination product of the TAAP™ and MPAR® (Multi-Pill Abuse Resistance) technology to treat severe pain with the added benefit of oral overdose protection. PF614-MPAR combines prodrug PF614 with a trypsin inhibitor to reduce or "switch off" the release of the opioid in an overdose situation. Data from the initial clinical trial PF614-MPAR-101, demonstrating that the MPAR® technology worked as designed to provide the desired overdose protection to PF614-MPAR at a 25 mg dose, led to the FDA's Breakthrough Therapy designation in January 2024.

During the second quarter of 2025, the Company announced the completion of Part 1 of its second clinical trial, PF614-MPAR-102, that evaluated higher doses of PF614-MPAR for overdose protection. This Part of the study confirmed the earlier data from PF614-MPAR-101, showing that MPAR® technology can reduce risk from excessive doses when consumed accidentally or deliberately. The Company has now progressed to Part 2 of the three-part study and will examine whether there are any food effects on this MPAR® technology. The aggregate data will allow the Company to focus on perfecting a final drug product to move into commercialization and will be discussed with the FDA in an upcoming regulatory meeting.

Opioid Use Disorder (OUD) Program Update

In addition to pain management, Ensysce is advancing treatments for opioid use disorder, including innovative compounds that we believe will reduce cravings and block relapse without impairing quality of life. The Company has used its TAAP and MPAR® technology to provide what could be a safer methadone analogue to treat OUD. In 2024, a lead OUD drug candidate PF9001 was selected and has been evaluated for oral delivery, the potential for reduced cardiovascular side effects and overdose protection. The intent of the program is to provide a safer product to treat OUD, and to make OUD treatment more accessible to those who need it. The program, supported by a multi-year Helping to End Addiction Long-Term (HEAL) award, is planned to continue to non-clinical studies to support submission of an Investigational New Drug application in the future.

In another milestone for this program, the Company announced in April it had secured patent protection for the OUD platform. A Notice of Allowance from the U.S. Patent and Trademark Office was issued for a patent entitled: Enzyme-Cleavable Methadone Prodrugs and Methods of Use Thereof[1] which includes both composition of matter and method of use claims for PF9001.

Q1 2025 Financial Results

Cash – Cash and cash equivalents were $3.1 million as of March 31, 2025, compared to $3.5 million as of December 31, 2024. Subsequent to the end of the quarter, the Company received gross proceeds of $2.2 million, prior to deducting placement agent fees and offering expenses, from the exercise of warrants originally issued in March 2025.

Federal Grants – Funding under federal grants totaled $1.3 million for the first quarter of 2025 compared to $0.3 million in the comparable year ago quarter. The $1.0 million difference is due to the timing of research activities eligible for funding, with increased activities under the MPAR grant which began in September 2024.

Research & Development Expenses – R&D expenses were $1.9 million for the first quarter of 2025 compared to $0.8 million for the same period in 2024. The increase was primarily the result of external research and development costs related to PF614-MPAR, with increased pre-clinical activity in the 2025 period.

General & Administrative Expenses – G&A expenses were consistent at $1.4 million in the first quarter of both 2025 and 2024.

Other Income (Expense) – Total other income (expense) was income of $21,939 for the first quarter of 2025 compared to expense of $1.3 million in the same period of 2024. Other expense for the 2024 period consisted primarily of interest expense associated with the amortization of the original issue discount and debt issuance costs for convertible notes issued in 2023.

Net Income (Loss) – Net loss attributable to common stockholders for the first quarter of 2025 was $1.9 million compared to a net loss of $3.1 million for the first quarter of 2024. As a clinical stage biotech company, our continued research and development efforts toward regulatory approvals for our product candidates are expected to result in losses for the foreseeable future.

[1]The research covered by this patent was supported by the National Institute on Drug Abuse of the National Institutes of Health under Award Number UG3DA050271.

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage company with a goal of disrupting the analgesic landscape by introducing a new class of highly novel opioids for the treatment of severe pain. 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. 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, possible NASDAQ delisting, 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 annual report on Form 10-K 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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Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Federal grants	$ 1,319,772	$ 305,722
Operating expenses:		
Research and development	1,885,528	778,904
General and administrative	1,401,756	1,369,782
Total operating expenses	3,287,284	2,148,686
Loss from operations	(1,967,512)	(1,842,964)
Total other income (expense), net	21,939	(1,273,599)
Net loss	$ (1,945,573)	$ (3,116,563)
Adjustments to net loss	—	(216)
Net loss attributable to common stockholders	$ (1,945,573)	$ (3,116,779)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.39)	$ (8.21)

Ensysce Biosciences, Inc.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Net cash used in operating activities	$ (1,707,412)	$ (3,408,403)
Net cash provided by financing activities	1,257,826	5,689,148
Change in cash and cash equivalents	(449,586)	2,280,745
Cash and cash equivalents at beginning of period	3,502,077	1,123,604
Cash and cash equivalents at end of period	$ 3,052,491	$ 3,404,349

Ensysce Biosciences, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2025	**December 31, 2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 3,052,491	$ 3,502,077
Prepaid expenses and other current assets	1,348,500	1,842,605
Total current assets	4,400,991	5,344,682
Other assets	210,883	252,550
Total assets	$ 4,611,874	$ 5,597,232
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 615,295	$ 1,357,079
Accrued expenses and other liabilities	888,498	548,458
Notes payable and accrued interest	257,383	301,660
Total current liabilities	1,761,176	2,207,197
Long-term liabilities	130,180	10,096
Total liabilities	1,891,356	2,217,293
Stockholders' equity	2,720,518	3,379,939
Total liabilities and stockholders' equity	$ 4,611,874	$ 5,597,232