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): August 13, 2025 (August 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	**92037**
(Address of principal executive offices)	**(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 August 13, 2025, Ensysce Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 30, 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 August 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: August 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 Second Quarter 2025 Financial Results and Latest Program Updates

Initiates Critical Milestone, Launching Phase 3 Trial of PF614 to Advance Next-Generation Opioid Therapy Toward Regulatory Approval

Receives $5.3 Million Installment from NIDA To Support Overdose Protection Program

Accelerates PF614-MPAR-102 Study with Full Enrollment of Part 2

SAN DIEGO, CA / August 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 second quarter ended June 30, 2025.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "Momentum continued in the second quarter as we forged ahead progressing, what we believe will be the next evolution in opioid therapeutics: safety features built in to help guard against both misuse and overdose. The initiation of our pivotal Phase 3 trial for PF614 marks a major achievement for Ensysce and a critical step toward achieving our clinical and commercial strategy. This study is designed to validate PF614's ability to deliver what we believe will be superior pain relief for post-surgical pain with built-in abuse deterrence, reinforcing our commitment to developing safer opioid therapies. As we advance to seeking regulatory approval, PF614 has the potential to reshape the opioid treatment landscape and create long-term value for both patients and shareholders."

Dr. Kirkpatrick added, "Fully enrolling Part 2 of our PF614-MPAR-102 study marks another important step in progressing this product with built in overdose-protection. With continued financial support from NIDA and the FDA's Breakthrough Therapy designation, we are accelerating the development of what could be a game-changing solution for those in severe pain, one that not only has superior efficacy but is designed to prevent unintentional overdose."

"With the significant advancements made to date, we believe Ensysce is well-positioned to disrupt the opioid analgesic market with our lead candidates, PF614 and PF614-MPAR. Our approach leverages innovative chemistry to create opioid therapies that maintain strong efficacy while incorporating built-in safeguards against abuse and overdose. As we progress through the second half of the year, we are executing on a clear path of clinical and regulatory milestones across our TAAP™, MPAR®, and overdose use disorder (OUD) programs. With the opioid crisis continuing to take a devastating toll, our mission remains focused on saving lives and transforming how patients with pain and addiction are treated," Dr. Kirkpatrick concluded.

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 renders 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 a safer opioid product for those suffering from severe pain who require opioid-strength analgesia.

In July, Ensysce announced the initiation of its pivotal PF614-301 study evaluating PF614, to manage and moderate severe post-surgical pain after abdominoplasty. The study aims to demonstrate PF614's effectiveness in pain relief while minimizing the risk of abuse and supporting a safer transition to non-opioid outpatient care. Ensysce has engaged Rho, Inc., a clinical research organization with deep expertise in central nervous system (CNS) disorders and pain studies, to conduct the trial. The collaboration marks a major step toward redefining pain therapy with a safer class of opioids.

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 completed enrollment for Part 2 of its PF614-MPAR-102 study, to examine how food affects its MPAR technology, and is awaiting final data. The study is continuing with the third part of the trial through end of year and the Company is continuing to complete non-clinical studies required to support its use for chronic pain. PF614-MPAR, which combines Ensysce's TAAP™ and MPAR® technologies, has received FDA Breakthrough Therapy designation for its potential to prevent overdose while maintaining pain relief. Supported by a multi-year grant from the National Institute on Drug Abuse (NIDA), the program is advancing toward a new class of opioids designed to reduce the risks of abuse and overdose, a major step toward transforming pain management.

OUD Program Update

In addition to its pain management pipeline, Ensysce is advancing innovative treatments for opioid use disorder, including novel compounds designed to reduce cravings and prevent relapse without compromising quality of life. Leveraging its proprietary TAAP™ and MPAR® technologies, the Company is developing what may be a safer methadone alternative. In 2024, Ensysce selected PF9001 as its lead OUD candidate, evaluating it for oral delivery, reduced cardiovascular risk, and built-in overdose protection. Supported by a multi-year HEAL (Helping to End Addiction Long-Term) grant from NIDA, the program is progressing toward non-clinical studies to support a future Investigational New Drug (IND) application. In a key milestone during the quarter, Ensysce also received a Notice of Allowance from the U.S. Patent and Trademark Office for a patent covering the composition and use of PF9001, further strengthening its intellectual property position in the OUD space.

Q2 2025 Financial Results

Cash – Cash and cash equivalents were $2.2 million as of June 30, 2025, compared to $3.5 million as of December 31, 2024. During the quarter, the Company was awarded the second $5.3 million installment of a $15 million, three-year grant from the National Institute on Drug Abuse (NIDA)[1]. These funds are available for reimbursement of research and development expenses under the MPAR program through May 2026.

Federal Grants – Funding under federal grants totaled $1.4 million for the second quarter of 2025, compared to $0.2 million in the same quarter of 2024. The $1.2 million difference is due to the timing of research activities eligible for funding, with increased clinical activities in 2025 for the PF614-MPAR-102 study under the MPAR grant which began in September 2024.

Research & Development Expenses – R&D expenses were $1.9 million for the second quarter of 2025 compared to $0.9 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 and clinical activity in the 2025 period.

General & Administrative Expenses – G&A expenses were constant at $1.2 million in the second quarter of both 2025 and 2024.

Other Income (Expense) – Total other income (expense) was income of $16,998 for the second quarter of 2025 compared to expense of $12,351 in the same period of 2024.

Net Income (Loss) – Net loss attributable to common stockholders for the second quarter of 2025 was $1.7 million compared to a net loss of $2.0 million for the second quarter of 2024. As a clinical-stage biotech company, the Company's continued research and development efforts toward regulatory approvals for its product candidates are expected to result in losses for the foreseeable future.

[1]The research is supported by the National Institute on Drug Abuse of the National Institutes of Health under Award Number UO1DA059791.

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; continuation of government funding; 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 quarterly report on Form 10-Q and current reports on Form 8-K, 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 June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Federal grants	$ 1,371,438	$ 181,797	$ 2,691,210	$ 487,519
Operating expenses:				
Research and development	1,923,430	947,229	3,808,957	1,726,133
General and administrative	1,198,523	1,190,010	2,600,279	2,559,791
Total operating expenses	3,121,953	2,137,239	6,409,236	4,285,924
Loss from operations	(1,750,515)	(1,955,442)	(3,718,026)	(3,798,405)
Total other income (expense), net	16,998	(12,351)	38,936	(1,285,951)
Net loss	$ (1,733,517)	$ (1,967,793)	$ (3,679,090)	$ (5,084,356)
Net loss attributable to noncontrolling interest and deemed dividend related to warrants down round provision	166	—	166	(216)
Net loss attributable to common stockholders	$ (1,733,351)	$ (1,967,793)	$ (3,678,924)	$ (5,084,572)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.79)	$ (3.35)	$ (2.04)	$ (9.98)

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2025	**2024**
Net cash used in operating activities	$ (4,414,280)	$ (5,718,294)
Net cash provided by financing activities	3,123,778	5,637,921
Change in cash and cash equivalents	(1,290,502)	(80,373)
Cash and cash equivalents at beginning of period	3,502,077	1,123,604
Cash and cash equivalents at end of period	$ 2,211,575	$ 1,043,231

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

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 2,211,575	$ 3,502,077
Prepaid expenses, unbilled receivable and other current assets	3,070,020	1,842,605
Total current assets	5,281,595	5,344,682
Other assets	292,860	252,550
Total assets	$ 5,574,455	$ 5,597,232
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,042,832	$ 1,357,079
Accrued expenses and other liabilities	1,045,657	548,458
Notes payable and accrued interest	424,521	301,660
Total current liabilities	2,513,010	2,207,197
Long-term liabilities	1,033	10,096
Total liabilities	2,514,043	2,217,293
Stockholders' equity	3,060,412	3,379,939
Total liabilities and stockholders' equity	$ 5,574,455	$ 5,597,232