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): March 10, 2025 (March 10, 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 March 10, 2025, Ensysce Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter and year ended December 31, 2024. 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 March 10, 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: March 10, 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 Fourth Quarter and Full Year 2024 Financial Results

Secures Strategic Partnership for the Development and Commercial Launch of PF614 and PF614-MPAR

Groundbreaking Trial on PF614-MPAR Generates Positive Interim Results

SAN DIEGO, CA / March 10, 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 fourth quarter and full year ended December 31, 2024.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "Our team continued to make significant strides in the fourth quarter to deliver what we believe are the 'Next Generation' opioid analgesics with both abuse and overdose protection. We received feedback from the FDA on our PF614 phase 3 study design and are now taking steps to prepare for the expected start of enrollment of this clinical study in the second quarter of 2025. We are finalizing the selection of clinical sites and an experienced team to execute our PF614 phase 3 trial to remain on track to submit our PF614 New Drug Application in 2026."

Dr. Kirkpatrick continued, "Additionally, we are pleased with the continued positive results from our PF614-MPAR-102 study, showing PF614-MPAR provides overdose protection across our planned dosage range, when a greater-than-prescribed dose is consumed at one time. This second study of our overdose protection MPAR technology is continuing to evaluate subjects at higher dose limits in part 1 of the three-part study. The clinical trial is supported by our multi-year award from the National Institute on Drug Abuse and will continue to enroll subjects for parts 2 and 3 over the next year. Furthermore, in January, we entered into a highly valuable strategic partnership for the manufacture and commercial launch of both our PF614 and PF614-MPAR drug products.

I'm pleased that Ensysce concluded 2024 and entered 2025 in a very favorable position. We are encouraged by the FDA's recent focus on commercialization of new drug products that address and treat pain. With the "clever chemistry" of our lead products PF614 and PF614-MPAR, Ensysce is planning to disrupt the analgesic market, offering novel protection against overdose and abuse with opioid-grade efficacy."

TAAP™ (Opioid Abuse Deterrent Program) Update

Our 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 Company's TAAP™ technology is designed to control release, be highly resistant to tampering, and reduce abuse, with a goal of providing what the company believes is a safer effective opioid product for those suffering with severe pain who require opioid-strength analgesia.

During the fourth quarter, the Company announced its strategic partnership with a leading specialty drug manufacturer to push manufacture of PF614 to commercial launch and for the development of a PF614-MPAR final drug product. This collaboration establishes readiness and a shared commitment to achieving swift regulatory approval with efficient development of the initial commercial supply of the Company's highly innovative drug products, PF614 and PF614-MPAR.

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

PF614-MPAR, the Company's second product to treat severe pain with the added benefit of oral overdose protection, is a combination product of the TAAP™ prodrug PF614 with a trypsin inhibitor. MPAR® (Multi-Pill Abuse Resistance) reduces or "switches off" the release of the opioid only in an overdose situation, by blocking the first step of the trypsin activation process, providing an additional layer of protection to Ensysce's TAAP™ medications. Data from the clinical trial, PF614-MPAR-101, demonstrating that the MPAR® technology worked as designed to provide overdose protection, led to the FDA's Breakthrough Therapy designation in January 2024.

During the fourth quarter, the Company initiated a second clinical trial with PF614-MPAR, PF614-MPAR-102, to evaluate higher dosages of PF614-MPAR. In January, the Company announced interim data from PF614-MPAR-102 that showed a 100 mg dosage form of PF614-MPAR provided overdose protection when a greater-than-prescribed dose is consumed at one time. The study continues to examine the protection provided when 5 times the 100 mg dose unit is consumed, studying potential food effects, and conducting a multiple ascending dose study with the final PF614-MPAR combination. Thus far, adverse events have been limited, we believe verifying the favorable safety profile of PF614 and PF614-MPAR as a novel class of opioids to treat severe pain.

Opioid Use Disorder (OUD) Program Update

Using its TAAP technology, the Company created a pipeline of methadone analogues to treat OUD, and in 2024 selected its lead OUD drug candidate PF9001. The intent of the program is to reduce both the abuse profile and the cardiovascular side effects associated with traditional methadone OUD treatments, 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 continuing non-clinical studies to support moving into IND enabling work in the coming year.

Q4 & Full Year 2024 Financial Results

Cash – Cash and cash equivalents were $3.5 million as of December 31, 2024, compared to $4.2 million as of September 30, 2024 and $1.1 million as of December 31, 2023. For the year, cash from financing activities of $9.9 million exceeded cash used in operations of $7.5 million.

Federal Grants – Funding under federal grants totaled $1.3 million for the fourth quarter of 2024 compared to $0.5 million in the comparable year ago quarter. For the full year of 2024, funding from federal grants was $5.2 million compared to $2.2 million for the full year of 2023. The increased funding in 2024 is largely attributable to a $14 million multi-year award from the National Institute on Drug Abuse (NIDA) to support the MPAR clinical program. The remaining cash funding under the MPAR grant is $1.6 million for the period through May 31, 2025, with an additional $9.0 million of funding available for the following two years.

Research & Development Expenses – R&D expenses were $3.8 million for the fourth quarter of 2024 compared to $2.2 million for the same period in 2023. The increase was due to heightened activity for the MPAR and OUD programs in 2024. For the full year, R&D expenses were $7.2 million compared to $7.6 million for 2023. The full year decrease was primarily the result of reduced costs related to clinical and pre-clinical programs for PF614 as activity in 2024 transitioned to preparation for a Phase 3 trial.

General & Administrative Expenses – G&A expenses were $1.1 million in the fourth quarter of 2024, compared to $1.4 million for the fourth quarter of 2023. For 2024, G&A expenses were $4.7 million, representing a decrease of $0.6 million compared to $5.4 million for 2023. The decrease was primarily a result of reduced stock-based compensation expenses in 2024. We expect future general and administrative expenses to approximate current levels.

Other Income (Expense) – Total other income (expense) was income of $12,054 for the fourth quarter of 2024 compared to expense of $0.3 million in the same period of 2023. For 2024, total other income (expense), net was an expense of $1.3 million compared to income of $0.1 million for 2023. The changes in other expenses were primarily the

result of interest expense associated with the amortization of the original issue discount and the debt issuance costs for the 2023 Notes and represented a net change in other income and expense of $1.3 million compared to 2023.

Net Income (Loss) – Net loss attributable to common stockholders for the fourth quarter of 2024 was $3.6 million compared to a net loss of $3.5 million for the fourth quarter of 2023. For 2024, net loss was $8.0 million compared to $10.6 million for 2023. 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Federal grants	$ 1,303,659	$ 515,032	$ 5,210,031	$ 2,230,520
Operating expenses:				
Research and development	3,802,630	2,232,760	7,219,437	7,587,473
General and administrative	1,077,505	1,437,957	4,720,728	5,361,234
Total operating expenses	4,880,135	3,670,717	11,940,165	12,948,707
Loss from operations	(3,576,476)	(3,155,685)	(6,730,134)	(10,718,187)
Total other income (expense), net	12,054	(348,676)	(1,256,875)	91,912
Net loss	$ (3,564,422)	$ (3,504,361)	$ (7,987,009)	$ (10,626,275)
Adjustments to net loss	—	66	(216)	264
Net loss attributable to common stockholders	$ (3,564,422)	$ (3,504,295)	$ (7,987,225)	$ (10,626,011)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.90)	$ (16.94)	$ (11.45)	$ (70.40)

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2024	2023
Net cash used in operating activities	$ (7,502,700)	$ (10,779,982)

Net cash provided by financing activities	9,881,173	8,755,884
Change in cash and cash equivalents	2,378,473	(2,024,098)
Cash and cash equivalents at beginning of period	1,123,604	3,147,702
Cash and cash equivalents at end of period	$ 3,502,077	$ 1,123,604

Ensysce Biosciences, Inc.
Condensed Consolidated Balance Sheets

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 3,502,077	$ 1,123,604
Prepaid expenses and other current assets	1,842,605	1,165,264
Total current assets	5,344,682	2,288,868
Other assets	252,550	419,217
Total assets	$ 5,597,232	$ 2,708,085
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,357,079	$ 1,936,007
Accrued expenses and other liabilities	548,458	542,260
Notes payable and accrued interest	301,660	854,697
Total current liabilities	2,207,197	3,332,964
Long-term liabilities	10,096	26,388
Total liabilities	2,217,293	3,359,352
Stockholders' deficit	3,379,939	(651,267)
Total liabilities and stockholders' equity	$ 5,597,232	$ 2,708,085