
**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, 2026 (August 13, 2026)

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 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, 2026, Ensysce Biosciences, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended June 30, 2026. 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, 2026
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, 2026

Ensysce Biosciences, Inc.

By: /s/ Lynn Kirkpatrick

Name: Dr. Lynn Kirkpatrick

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

Ensysce Biosciences Reports Second Quarter 2026 Financial Results and Recent Business Highlights

~ Acquisition of Cy Biopharma Completed, Adding CY200 for Complex Regional Pain Syndrome ~

~ Up to \$77 million in new funding with the acquisition of Cy Biopharma ~

~ Company to host a Corporate Update Call on Tuesday, August 18, 2026, at 11:00 a.m. ET ~

SAN DIEGO, CA / August 13, 2026 / Ensysce Biosciences, Inc. (NASDAQ: ENSC) (“Ensysce” or the “Company”), a clinical-stage biotechnology company developing novel neuroplastogenic therapies beyond mood disorders, with an initial focus on complex pain, today reported financial and operational results for the second quarter ended June 30, 2026.

On August 6, 2026, we completed the acquisition of Cy Biopharma, Inc. (“Cy Biopharma”) with private placement financings of \$38.6 million, adding CY200, an Orphan Drug-designated candidate for Complex Regional Pain Syndrome (CRPS), to be our lead pipeline asset. We now have cash runway into late 2027, and a second financing tranche of up to \$38.6 million, triggered upon achievement of certain clinical milestones, would carry the company into 2028.

The acquisition was a stock-for-stock merger that brought in \$17.1 million in cash from Cy Biopharma’s pre-acquisition convertible note financing. Concurrent with the acquisition, Ensysce entered into a definitive agreement for the sale of Series C non-voting convertible preferred stock in a private placement financing with gross proceeds to the Company of approximately \$21.5 million before deducting transaction expenses. The private placement financing was led by Ally Bridge Group and included participation from Perceptive Advisors, Dellora Investments, Ikarian Capital and Adage Capital Partners, L.P.

Complex Regional Pain Syndrome (CRPS) Program Update

With the acquisition of Cy Biopharma, the Company added CY200, a clinical-stage neuroplastogenic candidate for the treatment of CRPS Type 1, which has received U.S. FDA Orphan Drug Designation. CRPS is among the most severe chronic pain disorders, with few effective treatment options and significant physical, psychological, and socioeconomic burden, and there is currently no approved therapy for the condition. Rather than managing symptoms alone, CY200 is designed to address the underlying neurobiology of CRPS. The Company intends to apply proceeds from the private placement financings primarily to advance CY200 through a randomized Phase 2 trial evaluating efficacy, safety and tolerability for symptom alleviation in participants with CRPS Type 1, and to prepare for registrational development.

“Cy Biopharma’s neuroplastogenic approach to complex pain was the most compelling strategic opportunity we explored, and we believe this acquisition represents a significant value creation opportunity for Ensysce stockholders. The concurrent private placement financing was intentionally sized to support our immediate strategic objectives while maintaining financial discipline and allow us to progress our lead candidate in a pain market valued over \$1 billion for which there is currently no approved therapy,” said Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce. “During the second quarter of 2026 we also advanced the clinical development of PF614-MPAR, the first opioid engineered with built-in overdose protection. To support this clinical development, we were awarded the third year of funding under a \$15.1 million grant from the National Institute on Drug Abuse (NIDA), completing the award, a powerful vote of confidence from a leading federal agency that has backed this program with two major awards totaling over \$26 million over six years.”

TAAPT[™] and MPAR[®] (Opioid Abuse Deterrent and Overdose Protection Programs) Update

Trypsin-Activated Abuse Protection (TAAPT[™]) PF614 represents what we believe could be a next-generation extended-release oxycodone with built-in abuse protection. PF614 remains inactive until it is swallowed and exposed to trypsin in the small intestine, where it “switches on” to release oxycodone in a controlled manner, providing what we believe is improved safety. Development of PF614 continues with the pivotal PF614-301 Phase 3 clinical trial, a multicenter, randomized, double-blind, placebo-controlled study evaluating PF614 for the treatment of moderate to severe pain following abdominoplasty.

PF614-MPAR is a combination product that integrates both the TAAPT[™] and MPAR[®] (Multi-Pill Abuse Resistance) technologies to deliver effective opioid analgesia with the added benefit of built-in oral overdose protection, and has received FDA’s Breakthrough Therapy designation. Ensysce has continued to enroll subjects in the PF614-MPAR-102 study, supported by the NIDA grant, reflecting ongoing external validation of the program’s potential impact. As of June 30, 2026, \$5.3 million of funding remained available through May 2027 under the grant.

Ensysce also strengthened its intellectual property position for MPAR[®] during the quarter. In May 2026, the Taiwan Intellectual Property Office issued a patent titled “Compositions Comprising Enzyme-Cleavable Prodrugs and Controlled Release Nafamostat and Methods of Use Thereof,” extending MPAR[®] patent protection through 2042 in that jurisdiction and expanding on U.S. Patent No. 12,599,578, which issued April 14, 2026.

Q2 2026 Financial Results

Cash - Cash and cash equivalents were \$0.7 million as of June 30, 2026, compared to \$4.3 million as of December 31, 2025. The decrease reflects \$5.5 million of cash used in operating activities during the first six months of 2026, partially offset by \$1.8 million of net proceeds from a preferred stock financing. Following quarter-end, the acquisition of Cy Biopharma and related financings provided cash of approximately \$31 million, net of transaction expenses.

Federal Grants - Funding under federal grants totaled \$1.2 million for the second quarter of 2026 compared to \$1.4 million in the comparable year ago quarter. This \$0.2 million decrease is primarily due to the timing of research activities eligible for funding under the MPAR grant.

Research & Development Expenses - R&D expenses were \$2.5 million for the second quarter of 2026 compared to \$1.9 million for the same period in 2025, representing an increase of \$0.5 million. The increase was primarily the result of external research and development costs related to increased clinical activity for PF614.

General & Administrative Expenses - G&A expenses were \$1.3 million in the second quarter of 2026 and \$1.2 million for the second quarter of 2025, representing an increase of \$0.1 million.

Other Income (Expense) - Total other income (expense) was income of \$5,514 for the second quarter of 2026 compared to income of \$16,998 in the same period of 2025. Total other income (expense) for the quarters ended June 30, 2026 and June 30, 2025, consisted primarily of interest income from cash and cash equivalents.

Net Income (Loss) - Net loss attributable to common stockholders for the second quarter of 2026 was \$2.6 million compared to a net loss of \$1.7 million for the second quarter of 2025. 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. Results for periods after June 30, 2026, will reflect the acquisition of Cy Biopharma and related transaction expenses, and are therefore not comparable to the periods presented.

Corporate Update Conference Call

CEO, Dr. Lynn Kirkpatrick, President, James Morrison, and Cy Biopharma CMO, Professor Richard Langford, will host a conference call on Tuesday, August 18, 2026, at 11:00 a.m. ET to provide a corporate update, including the recently completed acquisition of Cy Biopharma.

Date: Tuesday, August 18, 2026

Time: 11:00 a.m. ET

U.S. Dial-in: 1-877-407-9716

International Dial-in: 1-201-493-6779

Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1772527&tp_key=742e115fc1

Please dial in at least 10 minutes before the start of the call to ensure timely participation. A playback of the call will be available through Friday, September 18, 2026. To listen, call 1-844-512-2921 within the United States and Canada or 1-412-317-6671 when calling internationally. Please use the replay access ID 13762262.

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage biotechnology company developing novel neuroplastogenic therapies using psychedelics that go beyond mood disorders and address the root cause of chronic pain through central nervous system modulation. The company is also developing a new class of highly novel opioids for the treatment of severe pain while minimizing the risk of both drug abuse and overdose. For more information, please visit www.ensysce.com.

Definitions

CRPS: complex regional pain syndrome - a severe chronic pain disorder for which there is currently no approved therapy.

TAAPT[™]: 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,	
	2026	2025	2026	2025
Federal grants	\$ 1,164,315	\$ 1,371,438	\$ 2,125,313	\$ 2,691,210
Operating expenses:				
Research and development	2,471,752	1,923,430	5,818,633	3,808,957
General and administrative	1,268,952	1,198,523	2,445,299	2,600,279
Total operating expenses	3,740,704	3,121,953	8,263,932	6,409,236
Loss from operations	(2,576,389)	(1,750,515)	(6,138,619)	(3,718,026)
Total other income (expense), net	5,514	16,998	11,329	38,936
Net loss	\$ (2,570,875)	\$ (1,733,517)	\$ (6,127,290)	\$ (3,679,090)
Adjustments to net loss	166	166	166	166
Net loss attributable to common stockholders	\$ (2,570,709)	\$ (1,733,351)	\$ (6,127,124)	\$ (3,678,924)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.20)	\$ (0.79)	\$ (0.62)	\$ (2.04)

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

	Six Months Ended June 30,	
	2026	2025
Net cash used in operating activities	\$ (5,463,383)	\$ (4,414,280)
Net cash provided by financing activities	1,829,733	3,123,778
Change in cash and cash equivalents	(3,633,650)	(1,290,502)
Cash and cash equivalents at beginning of period	4,310,354	3,502,077
Cash and cash equivalents at end of period	\$ 676,704	\$ 2,211,575

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

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 676,704	\$ 4,310,354
Prepaid expenses and other current assets	2,169,506	2,934,664
Total current assets	2,846,210	7,245,018
Other assets	111,063	207,461
Total assets	<u>\$ 2,957,273</u>	<u>\$ 7,452,479</u>
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,977,629	\$ 3,267,610
Accrued expenses and other liabilities	1,893,635	993,411
Notes payable and accrued interest	196,842	306,708
Total current liabilities	4,068,106	4,567,729
Long-term liabilities	—	—
Total liabilities	4,068,106	4,567,729
Stockholders' equity (deficit)	(1,110,833)	2,884,750
Total liabilities and stockholders' equity (deficit)	<u>\$ 2,957,273</u>	<u>\$ 7,452,479</u>