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 11, 2023 (August 11, 2023)

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 August 11, 2023, Ensysce Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 30, 2023. 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 11, 2023.
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 11, 2023

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 2023 Financial Results

~ Progression Toward Full Phase 3 Evaluation of PF614 with Recently Announced IRB Approval of Key Study Protocol ~

SAN DIEGO, CA, August 11, 2023 — Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ: ENSC), a clinical-stage company applying transformative chemistry to improve prescription drug safety, today reported financial results for the second quarter of 2023.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "The recently announced IRB approval of the PF614-201 protocol gives us confidence in the momentum we have achieved to date, bringing us closer to our Phase 3 evaluation of PF614. We believe the unique chemistry we have designed around opioids will ultimately lead to a new generation of pain products to alleviate the suffering of those who experience severe pain. We expect our goal to develop both PF614 and PF614-MPAR and expand the use of our two core technologies will be advanced by the recently announced engagement of Alacrita Consulting to explore partnering and licensing opportunities."

TAAP™ (Opioid Abuse Deterrent Program) Updates

Our lead product, PF614, is a Trypsin-Activated Abuse Protection (TAAP™) extended-release oxycodone and a potential 'next generation' analgesic for severe pain. The Company's TAAP™ technology is designed to control release, be highly resistant to tampering and reduce abuse through a unique chemical modification. PF614's TAAP™ modification makes it inactive until it is swallowed, following which it is activated or 'turned on' to release oxycodone by the body's own trypsin, an enzyme in the small intestine. Ensysce completed three clinical trials over the last year and believes it has a body of evidence showing that PF614 works as designed, is bioequivalent to OxyContin and has a good safety profile. Our most recent studies demonstrate that PF614 is less liked by recreational drug users when taken orally as compared to regular oxycodone, so we believe it is less likely to be abused.

Most recently, on August 8, 2023, the Company announced the Investigational Review Board ("IRB") approval of the PF614-201 protocol, 'A Randomized, Double-Blind, Placebo-Controlled Crossover Study of PF614 on Analgesic Response in the Cold Pressor Test in Healthy Male Subjects.' This represents yet another key milestone for PF614 in its development pathway. The Company believes the requirement for exposure to trypsin and the chemically designed release kinetics distinguish PF614 from other marketed oxycodone drug products.

On April 3, 2023, the Company announced positive results from PF614-104, a study that evaluated the oral abuse potential of PF614. The study met all key endpoints and showed that oral administration of PF614 had significantly lower scores for "Drug Liking" and willingness to "Take Drug Again" than the oxycodone comparator. The completion of this trial, in addition to the PF614-102 and PF614-103 trials now positions PF614 for an End of Phase 2 meeting with the FDA, anticipated later this year and initiating our Phase 3 strategy in 2024.

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

PF614-MPAR is a combination product to treat severe pain, designed with overdose protection. MPAR® (Multi-Pill Abuse Resistance) reduces or 'turns off' the release of the opioid in an overdose situation, providing the additional layer of protection to Ensysce's TAAP™ medications. We believe that MPAR® is the first technology that may reduce prescription drug overdoses stemming from oral abuse and that it can save lives. The clinical data generated over the past year shows that the MPAR® combination technology reduces release and absorption of oxycodone from PF614, specifically in an overdose situation. We are now positioned to have a meeting with the FDA to discuss the MPAR® overdose protection program and our full dose range of PF614-MPAR drug products.

On May 9, 2023, the Company announced the successful completion of overdose protection Phase 1 study, PF614-MPAR-101. The final Part B of the study examined dose escalation of PF614-MPAR and successfully showed that PF614-MPAR delivered oxycodone appropriately when one or two doses were consumed yet reduced opioid delivery when three or more doses are consumed simultaneously, in a simulated overdose situation.

We believe that the clinical results from Ensysce's programs indicate that both PF614 and PF614-MPAR represent important improvements for severe pain management, an issue that has greatly impacted the United States in recent years where access to prescriptions of these strong pain medications has been affected by the opioid crisis.

Second Quarter 2023 Financial Results

- **Cash –** Cash and cash equivalents were $3.8 million as of June 30, 2023, as compared to $1.4 million as of March 31, 2023. The net increase in cash primarily results from a public offering on May 12, 2023, with gross proceeds of $7.0 million before deducting placement agent fees and other offering expenses, less operating expenses for the quarter.
- **Federal Grants -** Funding under federal grants increased to $0.5 million for the second quarter of 2023 compared to $0.2 million in the comparable year ago quarter. The increase is due to the timing of research activities eligible for funding, particularly related to the MPAR® program.
- **Research & Development Expenses –** R&D expenses decreased to $1.6 million for the second quarter of 2023 compared to $5.3 million for the same period in 2022. The decrease was primarily the result of timing of external research and development costs related to clinical studies for PF614.
- **General & Administrative Expenses –** G&A expenses decreased to $1.1 million for the second quarter of 2023 compared to $1.9 million for the same period of 2022. The decrease was primarily due to reduced stock-based compensation and reduced costs associated with liability insurance in the 2023 period.
- **Other Income (Expense) –** Total other income (expense), net was income of $55,000 for the second quarter of 2023 compared to expense of $0.9 million for the same period of 2022. The change in other expenses is primarily due to non-cash fair value adjustments for convertible notes and warrants.
- **Net Loss –** Net loss attributable to common stockholders for the second quarter of 2023 was $2.2 million compared to $7.9 million for the second quarter of 2022. 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Federal grants	$ 490,472	$ 207,471	$ 1,280,107	$ 810,569
Operating expenses:				
Research and development	1,643,726	5,311,298	3,439,742	8,451,394
General and administrative	1,140,700	1,951,356	2,695,553	4,217,161
Total operating expenses	2,784,426	7,262,654	6,135,295	12,668,555
Loss from operations	(2,293,954)	(7,055,183)	(4,855,188)	(11,857,986)
Total other income (expense), net	54,652	(867,937)	424,080	2,983,942
Net loss	$ (2,239,302)	$ (7,923,120)	$ (4,431,108)	$ (8,874,044)
Adjustments to net loss	3,331	(76,170)	(1,037)	(791,932)
Net loss attributable to common stockholders	$ (2,235,971)	$ (7,999,290)	$ (4,432,145)	$ (9,665,976)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.98)	$ (56.49)	$ (2.66)	$ (75.67)

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

	Six Months Ended June 30,	
	2023	2022
Net cash used in operating activities	$ (6,715,461)	$ (7,877,508)
Net cash provided by investing activities	—	4,500
Net cash provided by (used in) financing activities	7,397,241	(657,082)
Change in cash and cash equivalents	681,780	(8,530,090)
Cash and cash equivalents at beginning of period	3,147,702	12,264,736
Cash and cash equivalents at end of period	$ 3,829,482	$ 3,734,646

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 3,829,482	$ 3,147,702
Prepaid expenses and other current assets	2,025,591	2,151,467
Total current assets	5,855,073	5,299,169
Other assets	502,550	585,883
Total assets	$ 6,357,623	$ 5,885,052
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,274,629	$ 2,943,791
Accrued expenses and other liabilities	796,753	2,253,809
Notes payable and accrued interest	445,738	4,266,610
Total current liabilities	2,517,120	9,464,210
Long-term liabilities	47,696	450,494
Total liabilities	2,564,816	9,914,704
Stockholders' equity (deficit)	3,792,807	(4,029,652)
Total liabilities and stockholders' equity (deficit)	$ 6,357,623	$ 5,885,052

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage company using its proprietary technology platforms to develop safer prescription drugs. 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. The platforms are covered by an extensive worldwide intellectual property portfolio for a wide array of prescription drug compositions. For more information, please visit www.ensysce.com.

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, 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 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 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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