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 12, 2022 (May 12, 2022)

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**
Warrants to purchase one share of Common Stock	**ENSCW**	**OTC Pink Open Market**

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 12, 2022, Ensysce Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended March 31, 2022. 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, including as a result of COVID-19, 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 12, 2022.
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 12, 2022

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 Provides Business Update and Reports First Quarter 2022 Financial Results

~ Corporate Update Call to be Held Tuesday, May 17, 2022 ~

SAN DIEGO, CA, May 12, 2022 — Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ: ENSC, OTC: ENSCW), a clinical-stage biotech company applying transformative chemistry to improve prescription drug safety and performance focused on reducing abuse and overdose, today reported financial results for the first quarter 2022.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "The first few months of 2022 are off to an exciting start, evident in the most recent clinical results from trials PF614-102 and PF614-MPAR-101. As we progress on our studies and clinical trials, we are closer to realizing our mission - providing abuse and overdose protection where needed. I look forward to our upcoming corporate update call next week to discuss the recent results from the trials, especially regarding the longer-lasting profile of PF614 and the encouraging initial data from our overdose protection study. Additionally, we expect the Bioequivalence (BE) trial data of our TAAP™ opioid, PF614, to be available prior to the end of the second quarter, positioning PF614 as our first commercial candidate and demonstrating progress towards our goal to bring a unique pipeline of products to the market."

TAAP™ (Opioid Abuse Deterrent Program) Updates

- On May 5, 2022, the Company announced clinical trial results from trial PF614-102 confirming the safety and longer-lasting profile of PF614 versus Oxycontin.
- The results of the study show the longer-lasting half-life of PF614 versus OxyContin as seen in the prior Phase 1 single-ascending dose study of PF614 oral solution versus OxyContin. We believe this data confirms the findings from our Phase 1 study that demonstrate PF614 should provide true twice-daily dosing.
- The safety data for the study also showed that PF614 performed similarly to OxyContin with no serious treatment emergent adverse events recorded.
- The second part of the PF614-102 study, the bioequivalence (BE) arm, continues to be analyzed and as reported previously, we anticipate that this BE data will be available by the end of the second quarter of 2022. The Company believes that the data will support the 505(b)(2) regulatory path for clinical development of PF614, an abbreviated pathway to FDA approval.
- Human abuse liability (HAL) studies to determine labeling claims for PF614 are scheduled to initiate in the second quarter of 2022.
- PF614 is designed using the abuse protective platform TAAP™, Trypsin Activated Abuse Protection, a chemical modification which inactivates the active ingredient in Ensysce's opioid products, including PF614, until swallowed and exposed to the enzyme trypsin in the digestive system. Our TAAP™ platform, which we believe provides abuse protection and resistance to manipulation and other forms of recreational drug abuse, should also control the rate of release of the active opioid.

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

- On May 5, 2022, the Company announced initial results from trial PF614-MPAR-101, providing first human data showing the potential for overdose protection with MPAR, Multi-Pill Abuse Resistance.
- This data demonstrated how the combination product PF614-MPAR could reduce the trypsin activation and reduce the release of oxycodone in a simulated overdose situation. It also demonstrated the PF614 in the systemic circulation (simulated injection) did not convert to oxycodone. We believe this is the first step to identifying the first MPAR drug product that will be marketed in the coming years.
- The study is continuing with additional subjects enrolling to receive PF614 and trypsin inhibitor nafamostat in various combinations through the third quarter of 2022. Safety and pharmacokinetic results are expected by the end of the third quarter 2022.

Financial Results

- **Cash –** Cash and cash equivalents were $8.4 million as of March 31, 2022, as compared to $12.3 million at December 31, 2021. Cash used in operating activities for the first quarter of 2022 totaled $3.4 million, an increase from $0.5 million in the first quarter of 2021 that primarily resulted from the clinical advancement of our product candidates and increased costs related to operating as a public company.
- **Federal Grants –** Funding from federal grants was $0.6 million for the first quarter of 2022 compared to $0.3 in the comparable year ago quarter. Funding increased by $0.4 million under the MPAR Grant, offset by a decrease of $0.1 million under the OUD Grant, due to the timing of research activities eligible for funding.
- **Research & Development Expenses –** R&D expenses were $3.1 million for the first quarter of 2022 compared to $0.3 million in the comparable year ago quarter. The increase was primarily the result of increased external research and development costs related to preclinical and clinical programs for PF614 and PF614-MPAR™.
- **General & Administrative Expenses –** G&A expenses were $2.3 million for the first quarter of 2022 compared to $0.5 million for the same period in 2021. The increase was primarily a result of increased expenses related to operating as a public company, including legal and accounting fees and director and officer insurance expenses.
- **Other Income (Expense) –** Total other income (expense), was income of $3.9 million in the first quarter of 2022 and expense of $0.4 million in the first quarter of 2021. The income in the 2022 period is due to non-cash valuation adjustments of current obligations of the Company. The 2021 expense primarily reflects non-cash interest expense on notes that were converted on June 30, 2021.
- **Net Income (Loss) –** Net loss for the first quarter of 2022 was $1.0 million compared to net loss of $0.9 million for the comparable year ago period. As we are a clinical stage biotech company, our research and development of, and regulatory approvals for, our product candidates are expected to continue, resulting in expected losses for the foreseeable future.

Additional Company Highlights

- On February 8, 2022, the Company added further depth to its Board of Directors with the appointment of Lee Rauch.
- On April 18, 2022, the Company announced the appointment of Dr. Nily Osman as Chief Medical Officer.

Corporate Update Conference Call

Management will host a corporate update conference call on Tuesday, May 17, 2022, at 11:00am ET to provide a corporate update and review the recently discussed results from Clinical Trials PF614-102 and PF614-MPAR-101. The call will conclude with Q&A from participants. An accompanying presentation will be posted prior to the call to the Company's investor relations website.

Date: Tuesday, May 17, 2022
Time: 11:00am ET
U.S. Dial-in: 1-877-407-0792
International Dial-in: 1-201-689-8263
Conference ID: 13729812
Webcast: ENSC Corporate Update Call

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 Tuesday, June 14, 2022. 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 pin number 13729812.

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Operations

	Three Months Ended March 31,	
	2022	**2021**
	(Unaudited)	(Unaudited)
Federal grants	$ 603,098	$ 250,576
Operating expenses:		
Research and development	3,140,096	284,378
General and administrative	2,265,806	490,471
Total operating expenses	5,405,902	774,849
Loss from operations	(4,802,804)	(524,273)
Total other income (expense), net	3,851,879	(387,419)
Net loss	$ (950,925)	$ (911,692)
Adjustments to net loss	(715,761)	3,961
Net loss attributable to common stockholders	$ (1,666,686)	$ (907,731)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.06)	$ (0.06)

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows

	Three Months Ended March 31,	
	2022	**2021**
	(Unaudited)	(Unaudited)
Net cash used in operating activities	$ (3,437,014)	$ (517,149)
Net cash provided by investing activities	4,500	—
Net cash provided by (used in) financing activities	(391,270)	612,862
Change in cash and cash equivalents	(3,823,784)	95,713
Cash and cash equivalents at beginning of period	12,264,736	194,214
Cash and cash equivalents at end of period	$ 8,440,952	$ 289,927

Ensysce Biosciences, Inc.
Condensed Consolidated Balance Sheets

	March 31, 2022	**December 31, 2021**
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 8,440,952	$ 12,264,736
Prepaid expenses and other current assets	3,217,450	3,397,857
Total current assets	11,658,402	15,662,593
Other assets	713,090	754,756
Total assets	$ 12,371,492	$ 16,417,349
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 959,630	$ 301,104
Accrued expenses and other liabilities	1,769,222	3,432,407
Notes payable and accrued interest	6,073,057	12,748,155
Total current liabilities	8,801,909	16,481,666
Long-term liabilities	2,458,310	8,093,741
Total liabilities	11,260,219	24,575,407
Stockholders' equity (deficit)	1,111,273	(8,158,058)
Total liabilities and stockholders' equity	$ 12,371,492	$ 16,417,349

About Ensysce Biosciences

Ensysce Biosciences, based in San Diego, CA is a clinical-stage biotech company using its two novel 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 seeking to develop next-generation, tamper-proof opioids that prevent both drug abuse and overdoses. Ensysce's products are anticipated to provide safer options to treat severe pain and assist in preventing deaths caused by opioid abuse, reducing the human and economic costs. The platforms are covered by an extensive worldwide intellectual property portfolio encompassing a wide array of prescription drugs. 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," and other similar expressions are intended to identify forward-looking statements. The product candidates discussed are in clinical development and are 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 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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