

**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): November 14, 2022 (November 14, 2022)

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 8.01 Other Events.

Ensysce Biosciences, Inc. has received guidance from the United States Food and Drug Administration and, on November 14, 2022, issued a press release about that guidance. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 14, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: November 14, 2022

Ensysce Biosciences, Inc.

By: /s/ Lynn Kirkpatrick

Name: Dr. Lynn Kirkpatrick

Title: President and Chief Executive Officer

Ensysce Biosciences Announces FDA Guidance on the Clinical Development Pathway for PF614

~ Acute pain indication may be appropriate, with potential to significantly shorten development path ~

San Diego, CA (November 14, 2022) Ensysce Biosciences Inc. (“Ensysce” or the “Company”) (NASDAQ:ENSC)(OTC PINK:ENSCW), a clinical-stage biotech company applying transformative chemistry to improve prescription drug safety focused on reducing abuse and overdose, today announced that it received written guidance from the FDA that an acute pain indication may be appropriate for the Company’s lead Trypsin Activated Abuse Protection (TAAP™) product, PF614.

The FDA guidance, while not binding, states that the Company’s proposed clinical development approach of conducting at least two adequate and well-controlled clinical trials in two different pain models comparing PF614 to placebo and to another immediate release (IR) opioid, such as IR oxycodone, appears reasonable to support a new drug application for PF614 for an acute pain indication. The FDA guidance also provides additional guidance with respect to the non-clinical studies and clinical trials planned by the Company.

The Company believes that the clinical development pathway of PF614 for an acute pain indication will reduce the development timeline and be more cost-effective than initially pursuing a chronic pain indication for PF614. Acute and sub-acute pain indications, based on the recent [CDC guidelines](#), are defined as pain lasting a duration of less than one or three months respectively. The Company intends to pursue development of PF614 for acute indications while continuing development of PF614 for use in chronic pain (pain lasting a duration of more than three months).

“As a result of the FDA guidance, we now intend to initially pursue clinical development of PF614 for an acute pain indication while continuing with our chronic pain development pathway. We believe that the longer half-life of PF614 compared to OxyContin may ultimately prevent acute pain from becoming chronic pain by better controlling severe pain on a day-to-day basis,” said Dr. Lynn Kirkpatrick, CEO of Ensysce. “We look forward to completing our human abuse potential studies and moving toward initiation of Phase 3 analgesic efficacy studies in the coming year.”

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage biotech 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 in the process of developing a unique, tamper-proof treatment option for pain that minimizes the risk of both drug abuse and overdose. Our products are anticipated to provide safer options to treat patients suffering from severe pain and assist in preventing deaths caused by medication abuse, reducing the human and economic costs. 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.

Ensysce Biosciences Company Contact:

Lynn Kirkpatrick, Ph.D.
Chief Executive Officer
(858) 263-4196

Ensysce Biosciences Investor Relations Contact:

Shannon Devine
MZ North America
Main: 203-741-8811
ENSC@mzgroup.us

SOURCE: Ensysce Biosciences Inc.
