

**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 16, 2021 (August 16, 2021)

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)

82-2757287
(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	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 16, 2021, Ensysce Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 30, 2021. 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 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”) (including filings as Leisure Acquisition Corp.). 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 16, 2021.

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 16, 2021

Ensycce Biosciences, Inc.

By: /s/ Lynn Kirkpatrick

Name: Dr. Lynn Kirkpatrick

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

Ensysce Biosciences Reports Second Quarter 2021 Financial Results and Recent Corporate Updates

SAN DIEGO, AUGUST 16, 2021 — Ensysce Biosciences, Inc. (“Ensysce” or the “Company”) (NASDAQ: ENSC, OTC: ENSCW), a clinical-stage biotech company with proprietary technology platforms to reduce the economic and social burden of prescription drug abuse and overdose, today reported financial results for the second quarter of 2021 and recent corporate updates.

“In the second quarter, we successfully closed our merger with Leisure Acquisition Corp., providing us with financial resources to advance our lead clinical programs and focus on expanding our pipeline of products in the pain, opioid use disorder (OUD) and ADHD space as a publicly listed company,” said Dr. Lynn Kirkpatrick, CEO of Ensysce Biosciences. “We currently have two technology platforms, TAAP and MPAR™, with three clinical-stage product candidates. Our pipeline of candidates provides us with the ability to grow each of these programs. Our focus is on prioritization and resource allocation to maintain an optimal balance between aggressively pursuing our more advanced clinical-stage product candidates, such as PF614, PF614-MPAR™, and nafamostat, while ensuring the continued development of additional potential product candidates. We have partnered with contract development and manufacturing organizations (CDMOs) to bolster our team and facilitate multiple parallel development programs. Our view, based on data so far and feedback from experts, is that our lead assets for chronic and severe pain have the potential to be transformational.”

Dr. Kirkpatrick concluded, “Over the long-term, it is our vision to develop the next generation of innovative solutions for severe pain relief while the reducing the fear of and the potential for opioid misuse, abuse and overdose.”

Program Updates

TAAP - opioid abuse deterrent program:

- Ensysce’s lead TAAP candidate, PF614, entered Phase 1b/Bioequivalence clinical development.
- Ensysce entered into an agreement for manufacture of PF614 clinical trial material with Recro Pharma.

MPAR - opioid overdose protection program:

- PF614-MPAR™, our overdose protection program lead product, received an Investigational New Drug (IND) allowance from the U.S. Food and Drug Administration.
- Notice of Award for year 3 of a multi-year grant was received from the National Institute on Drug Abuse (NIDA), providing Ensysce with additional resources to continue its work to bring PF614-MPAR™ into clinical development.
- PF614-MPAR™ entered Phase 1 clinical development utilizing a ‘translational pharmaceuticals’ approach.

Other programs:

- Ensysce entered into an agreement for manufacture of nafamostat clinical trial material with Recro Pharma for its COVID-19 oral therapy program.
- Ensysce received a Notice of Allowance from the United States Patent and Trademark Office for a patent entitled *Compositions Comprising Enzyme-Cleavable Amphetamine Prodrugs and Inhibitors Thereof*. This issuance provides the Company with additional pipeline candidates for ADHD indications.

Second Quarter 2021 Financial Results

- **Cash** - Cash and cash equivalents were \$8.0 million as of June 30, 2021. With the public listing of its common stock following the closing of the merger with Leisure Acquisition Corp. on June 30th, Ensysce now has access to a share subscription facility of up to \$60 million which it entered into in December 2020. As such, Ensysce believes it has access to sufficient capital to fund its current planned operations for at least the next twelve months.

- **Federal Grants** - Funding under federal grants was \$0.4 million for the second quarter of 2021 compared to \$1.8 million for the second quarter of 2020. The decrease is attributable to the timing of research activities eligible for funding.
- **R&D Expenses** - Research and development expenses were \$0.5 million for the second quarter of 2021 compared to \$1.4 million for the same period in 2020. The decrease was primarily resulted from reduced external research and development costs related to preclinical programs for PF614-MPAR™ and Phase 1 clinical trial activities of nafamostat.
- **G&A Expenses** - General and administrative expenses were \$0.4 million for the second quarter of 2021 compared to \$0.3 million for the second quarter of 2020. The increase was primarily a result of higher legal and other professional services expenses related to post-merger corporate matters.
- **Net Loss** - Net loss for the second quarter of 2021 was \$1.0 million compared to \$0.7 million for the same period in 2020.

About Ensysce Biosciences (NASDAQ: ENSC)

Ensysce Biosciences, San Diego, CA 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 developing a new class of powerful, 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 cost. 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

This press release contains certain forward-looking statements within the meaning of federal securities laws. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this communication. Such factors can be found in Ensysce’s most 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. Such factors can also be found in the Form S-4 and Ensysce’s definitive proxy statement/prospectus filed on June 16, 2021 and in the Form S-1 filed on August 9, 2021. New risks and uncertainties arise from time to time, and it is impossible for us to predict these events or how they may affect the Company. You are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made, and Ensysce undertakes no obligation to update or revise the forward-looking statements, whether as a result of new information, changes in expectations, future events or otherwise.

Investor Relations Contact:
Gateway Investor Relations
Matt Glover, Alex Thompson
(949) 574-3860
Ensysce@gatewayir.com

Ensysce Biosciences, Inc.
Unaudited Condensed Consolidated Statements of Operations

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Federal grants	\$ 444,516	\$ 1,824,681	\$ 695,091	\$ 2,687,081
Operating expenses:				
Research and development	463,219	1,404,246	787,595	2,243,217
General and administrative	393,914	281,354	884,386	559,047
Total operating expenses	<u>857,133</u>	<u>1,685,600</u>	<u>1,671,981</u>	<u>2,802,264</u>
Income (loss) from operations	(412,617)	139,081	(976,890)	(115,183)
Total other income (expense), net	<u>(544,994)</u>	<u>(845,555)</u>	<u>(932,413)</u>	<u>(1,614,538)</u>
Net loss	<u>\$ (957,611)</u>	<u>\$ (706,474)</u>	<u>\$ (1,909,303)</u>	<u>\$ (1,729,721)</u>

Ensysce Biosciences, Inc.
Unaudited Condensed Consolidated Balance Sheets

	<u>June 30,</u>	<u>December 31,</u>
	<u>2021</u>	<u>2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,011,782	\$ 194,214
Prepaid expenses and other current assets	346,286	153,662
Total current assets	<u>8,358,068</u>	<u>347,876</u>
Other assets	838,141	3,931
Total assets	<u>\$ 9,196,209</u>	<u>\$ 351,807</u>
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 3,140,721	\$ 1,724,598
Accrued expenses and other liabilities	422,141	370,292
Notes payable and accrued interest	466,055	4,245,082
Embedded derivative on convertible notes	—	670,262
Total current liabilities	<u>4,028,917</u>	<u>7,010,234</u>
Stockholders' equity (deficit)	5,167,292	(6,658,427)
Total liabilities and stockholders' equity	<u>\$ 9,196,209</u>	<u>\$ 351,807</u>