May 15, 2026

Ensysce Biosciences Reports First Quarter 2026 Financial Results

~ IRB Approval Secured for PF614-MPAR-102 Part 3 ~

~ Clinical Peer-Reviewed Data Published for First Overdose Protected Opioid PF614-MPAR®; Patent Estate Expanded ~

~ Company Launches Formal Review of Strategic Alternatives ~

SAN DIEGO, CA / ACCESS Newswire / May 15, 2026 /Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or the "Company"), a clinical-stage pharmaceutical company pioneering next-generation pain and central nervous system therapeutics engineered to minimize abuse and overdose risk, today reported financial and operational results for the first quarter ended March 31, 2026.

"The first quarter of 2026 delivered meaningful operational and clinical momentum across our pipeline, underscoring the strength of our strategy and the discipline of our execution," said Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce. We achieved 50% of the interim enrollment target in our pivotal PF614-301 Phase 3 trial, published the first peer-reviewed clinical data validating our MPAR® overdose-protection technology, and expanded our patent estate across both our opioid and ADHD programs. Together these milestones reinforce what we believe is the next evolution of opioid safety."

Dr. Kirkpatrick continued, "Following quarter-end, we closed a second financing tranche under an existing facility and secured IRB approval to initiate Part 3 of PF614-MPAR-102, the final stage of that study. Advancing this program strengthens the clinical evidence supporting a product we believe can fundamentally reshape how overdose risk is managed. In parallel, our Board has initiated a formal review of strategic alternatives, including potential partnerships and licensing opportunities, to accelerate the development of our TAAP™ and MPAR® platforms and unlock additional shareholder value."

TAAP™ (Opioid Abuse Deterrent Program) Update

PF614 is the Company's lead product candidate and represents what we believe could be a next-generation extended-release oxycodone with built-in abuse protection. Developed using our proprietary Trypsin-Activated Abuse Protection (TAAP™) technology, 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.

This targeted activation is designed to deliver effective pain relief while significantly reducing the potential for manipulation or non-oral abuse. By making the active drug inaccessible until it reaches the digestive tract, TAAP™ aims to provide a safer opioid option for patients with

severe pain who require opioid-strength therapy. The Company believes this approach has the potential to meaningfully differentiate PF614 within the multi-billion-dollar pain management market and address longstanding concerns around tampering and misuse.

In January, Ensysce announced that it had enrolled 50% of the subjects targeted for interim review in its 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. Enrollment, which began in late December 2025, progressed across two U.S. clinical sites; CenExel JBR (Salt Lake City, Utah) and CenExel Atlanta (Decatur, Georgia), under principal investigators Dr. Todd Bertoch and Dr. Jessica McCoun, recognized experts in anesthesiology and pain management. The study is designed to demonstrate PF614's ability to deliver consistent, clinically meaningful post-surgical pain relief using twice-daily dosing while leveraging its built-in abuse protection chemistry. Achieving the interim enrollment milestone in the early stages of the program brings Ensysce meaningfully closer to delivering interim data and advancing what the Company believes could be a new standard in acute pain management.

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

PF614-MPAR is the Company's next-generation combination product that integrates both the TAAP™ and MPAR® (Multi-Pill Abuse Resistance) technology to deliver effective opioid analgesia with the added benefit of built-in oral overdose protection. By pairing the PF614 prodrug with a trypsin inhibitor, PF614-MPAR is designed to "switch off" opioid release when supratherapeutic doses are taken, offering a differentiated safety profile aimed at reducing overdose risk while maintaining therapeutic efficacy for patients with severe pain.

Initial clinical data from the PF614-MPAR-101 study demonstrated that the MPAR® mechanism performed as intended at a 25 mg dose, providing the desired overdose protection. These results supported the FDA's decision to grant Breakthrough Therapy designation in January 2024, a key regulatory milestone that underscores the potential for PF614-MPAR to address a significant unmet need in opioid safety.

In March, Ensysce announced the publication of the first peer-reviewed clinical manuscript describing its MPAR® overdose protection technology in the January/February 2026 issue of the Journal of Opioid Management. The paper, "Formulation and a Phase 1 Clinical Study of PF614-MPAR, an Oxycodone Prodrug with Oral Opioid Overdose Protection," reported that PF614-MPAR achieved appropriate opioid plasma levels under normal dosing conditions while preventing large increases in exposure at supratherapeutic doses- reinforcing the potential for a fundamentally new safety paradigm in opioid analgesia.

Following quarter end, in April 2026, Ensysce received Institutional Review Board (IRB) approval to initiate Part 3 of the PF614-MPAR-102 study, the final stage in evaluating the MPAR® overdose-protection technology. Part 3 is designed to further characterize PF614-MPAR‘s protective effect across multiple dosing scenarios, building on the previously published data demonstrating that the product delivers therapeutic plasma levels under normal use while significantly limiting additional opioid exposure when higher-than-prescribed doses are taken. The study continues with support from the National Institute on Drug Abuse (NIDA), reflecting ongoing external validation of the program's potential impact.

ADHD Program Update

Ensysce is leveraging its TAAP™ and MPAR® platforms beyond pain management to develop what could become the first abuse-deterrent, overdose-protected stimulant therapies for attention-deficit/hyperactivity disorder (ADHD). The Company's ADHD pipeline includes PF8026, a novel immediate-release amphetamine prodrug, and PF8001, an extended-release candidate. In January 2026, Ensysce received a Notice of Allowance from the European Patent Office for a patent covering PF8026, with both composition-of-matter and method-of-use claims. This strengthens the Company's intellectual property position and supports long-term value creation as it allows advancement of safer stimulant options for a large and growing market. The need for innovation in ADHD therapeutics is significant. In 2023, approximately 3.9 million people aged 12 or older misused prescription stimulants, highlighting the limitations of current treatments and the urgency for products engineered to resist common routes of abuse and incorporate overdose protection mechanisms. By applying TAAP™ and MPAR® to stimulant medications, Ensysce has the ability to address this unmet need and expand its platform into another major therapeutic category with substantial commercial potential.

Opioid Use Disorder (OUD) Program Update

Beyond its pain management portfolio, Ensysce is advancing treatments for opioid use disorder (OUD) aimed at reducing cravings, lower relapse risk, and improving long-term patient outcomes while maintaining patient safety and quality of life. The Company has selected PF9001 as its lead OUD candidate and is evaluating it as a potential next-generation alternative to methadone, with the added advantage of built-in overdose protection, reduced cardiovascular risk and convenient oral delivery profile. The PF9001 program has been supported by a multi-year HEAL (Helping to End Addiction Long-Term) grant and in collaboration with NIDA. This program support provides both scientific validation and non-dilutive funding, reinforcing the potential of PF9001 to address critical gaps in current OUD treatment options and expand the application of Ensysce's TAAP™ and MPAR® technologies into another major public health challenge.

Q1 2026 Financial Results

Cash - Cash and cash equivalents were $0.7 million as of March 31, 2026, compared to $4.3 million as of December 31, 2025. Subsequent to March 31, 2026, on April 7, 2026, the Company closed a second tranche of $2.0 million in convertible preferred stock financing under its previously announced November 2025 commitment for up to $20 million over 24 months.

Federal Grants - Funding under federal grants totaled $1.0 million for the first quarter of 2026 compared to $1.3 million in the comparable year ago quarter. This $0.3 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 $3.3 million for the first quarter of 2026 compared to $1.9 million for the same period in 2025, representing an increase of $1.4 million. The increase was primarily the result of external research and development costs related to Phase 3 clinical trial activity for PF614.

General & Administrative Expenses - G&A expenses were $1.2 million in the first quarter of 2026 and $1.4 million for the first quarter of 2025, representing a decrease of $0.2 million.

Net Income (Loss) - Net loss attributable to common stockholders for the first quarter of 2026 was $3.6 million compared to a net loss of $1.9 million for the first 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.

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage company with a goal of disrupting the analgesic landscape by introducing a new class of highly novel opioids for the treatment of severe pain. 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. For more information, please visit www.ensysce.com.

Definitions

TAAP™: 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 annual report on Form 10-K 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 March 31,	
	2026	2025
Federal grants	$ 960,999	$ 1,319,772
Operating expenses:		
Research and development	3,346,881	1,885,528
General and administrative	1,176,348	1,401,756
Total operating expenses	4,523,229	3,287,284
Loss from operations	(3,562,230)	(1,967,512)
Total other income (expense), net	5,815	21,939
Net loss	$ (3,556,415)	$ (1,945,573)
Net loss per share, basic and diluted	$ (0.52)	$ (1.39)

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

	Three Months Ended March 31,	
	2026	2025
Net cash used in operating activities	$ (3,500,925)	$ (1,707,412)
Net cash (used in) provided by financing activities	(63,947)	1,257,826
Change in cash and cash equivalents	(3,564,872)	(449,586)
Cash and cash equivalents at beginning of period	4,310,354	3,502,077
Cash and cash equivalents at end of period	$ 745,482	$ 3,052,491

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

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 745,482	$ 4,310,354
Prepaid expenses and other current assets	1,263,058	2,934,664
Total current assets	2,008,540	7,245,018
Other assets	159,263	207,461
Total assets	$ 2,167,803	$ 7,452,479
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,610,186	$ 3,267,610
Accrued expenses and other liabilities	980,780	993,411
Notes payable and accrued interest	245,849	306,708
Total current liabilities	2,836,815	4,567,729
Long-term liabilities	-	-
Total liabilities	2,836,815	4,567,729
Stockholders' equity (deficit)	(669,012)	2,884,750
Total liabilities and stockholders' equity	$ 2,167,803	$ 7,452,479

SOURCE: Ensysce Biosciences

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