March 30, 2026

Ensysce Biosciences Reports Fourth Quarter and Full Year 2025 Financial Results

~ Fourth Quarter Highlighted by Clinical and Regulatory Milestones Positioning PF614 for Late-Stage Advancement ~

SAN DIEGO, CA / ACCESS Newswire / March 30, 2026 /Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or the "Company"), a clinical-stage pharmaceutical company developing innovative solutions for novel therapeutics while reducing the potential for abuse and overdose, today reported financial and operational results for the fourth quarter and full year ended December 31, 2025.

"2025 was a year of meaningful progress for Ensysce, marked by significant clinical advancement, productive regulatory engagement, and continued strengthening of our intellectual property portfolio," said Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce Biosciences. "We initiated our Phase 3 trial for PF614 and had constructive dialogue with the FDA supporting our manufacturing pathway."

Dr. Kirkpatrick continued, "Enrollment in the PF614-301 Phase 3 study has progressed rapidly, while PF614-MPAR remains on an accelerated development path under Breakthrough Therapy designation. In parallel, we have advanced commercial manufacturing readiness for PF614 and have generated additional data supporting overdose-protection labeling for our MPAR platform. Beyond our late-stage programs, we strengthened the long-term value of our technology platforms through expanded patent protection and pipeline growth, including the advancement of PF9001 for opioid use disorder (OUD) and leveraging our TAAP™ and MPAR® technologies for additional indications such as attention deficit hyperactivity disorder (ADHD)."

Program Updates

TAAP™ (Opioid Abuse Deterrent) Program Update

Ensysce's lead drug candidate, PF614, is a Trypsin-Activated Abuse Protection (TAAP™) extended-release oxycodone designed to deliver effective pain relief while incorporating built-in abuse protection. Through proprietary chemical modification of oxycodone, PF614 remains pharmacologically inactive until swallowed and exposed to trypsin in the small intestine, where it is activated to release oxycodone. This mechanism is designed to preserve therapeutic efficacy while significantly reducing the potential for tampering and abuse.

In December 2025, Ensysce announced the enrollment of the first patient in its pivotal Phase 3 clinical trial (PF614-301) evaluating PF614 for the treatment of moderate-to-severe post-

surgical pain following abdominoplasty. The multicenter, randomized, double-blind, placebo-controlled study is designed to assess whether PF614 can deliver potent and consistent analgesia while leveraging its unique chemical design to mitigate the risk of opioid misuse. Clinical sites currently enrolling patients include CenExel JBR in Salt Lake City, Utah, and CenExcel Atlanta under experienced principal investigators in anesthesiology and pain medicine. Enrollment in PF614-301 represents a major milestone in Ensysce's strategy to introduce a next generation of safer opioid medicines and advance PF614 toward regulatory submission and potential commercialization.

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

PF614-MPAR combines Ensysce's TAAP™ chemistry with its proprietary MPAR® (Multi-Pill Abuse Resistance) overdose-protection technology, designed to actively limit opioid release when multiple pills are consumed beyond prescribed doses. PF614-MPAR incorporates a trypsin inhibitor that automatically reduces opioid activation in overdose situations, effectively acting as a chemical "off-switch." Clinical data from the PF614-MPAR-101 study demonstrated that the MPAR® technology functioned as designed, providing overdose protection at a 25 mg dose. These results supported the FDA's Breakthrough Therapy designation granted in January 2024.

In November 2025, the FDA provided encouraging feedback regarding the development pathway for PF614-MPAR, including support for pursuing overdose-protection labeling and the potential use of a streamlined 505(b)(2) regulatory pathway, which could accelerate development and market entry. The FDA and Ensysce are collaborating on a framework to define and communicate the safety benefits of overdose-protection opioids, including development of a scientific whitepaper on overdose protection. This milestone, backed by multi-year grants from the National Institute on Drug Abuse (NIDA), marks a significant step toward transforming opioid safety and redefining pain management.

Opioid Use Disorder (OUD) Program Update

In addition to its pain management portfolio, Ensysce is developing treatments for opioid use disorder (OUD) designed to reduce cravings and relapse risk while maintaining patient safety and quality of life. The Company selected PF9001 as its lead OUD candidate and is evaluating the compound as a potential next-generation methadone alternative with built-in overdose protection, reduced cardiovascular risk and an oral delivery profile. This program was supported by a multi-year HEAL (Helping to End Addiction Long-Term) grant and in collaboration with NIDA.

Intellectual Property Expansion

In December 2025, the U.S. Patent and Trademark Office allowed a new patent covering Ensysce's MPAR® technology, further strengthening the Company's intellectual property protection through 2042. The patent, titled *"Compositions Comprising Enzyme-Cleavable Prodrugs and Controlled Release Nafamostat and Methods of Use Thereof,"* includes both composition-of-matter and method-of-use claims.

Ensysce is also exploring the application of MPAR technology beyond opioids, including potential programs in amphetamines for ADHD and methadone for OUD. In early January, Ensysce announced that the European Patent Office provided Notice of Allowance in

December 2025, for the issuance of a Patent 'Compositions Comprising Enzyme-Cleavable Amphetamine Prodrugs and Inhibitors Thereof' for PF8026 protected by the TAAP™ and MPAR® technologies. These two issuances expand the potential reach of Ensysce's platforms across multiple therapeutic areas where abuse and overdose risk remain significant clinical challenges.

Fourth Quarter and Full Year 2025 Financial Results

Cash - Cash and cash equivalents were $4.3 million as of December 31, 2025, compared to $3.5 million as of December 31, 2024. Cash used in operating activities totaled $7.8 million in 2025 compared to $7.5 million in 2024.

Federal Grants - Funding under federal grants totaled $1.9 million for the fourth quarter of 2025 compared to $1.3 million in the comparable year ago quarter. For the full year, funding from federal grants totaled $5.1 million in 2025, compared to $5.2 million in 2024. The differences are due to the timing of research activities eligible for funding under the OUD and MPAR grants, as decreases in funding under the OUD grant that ended in August 2024 were offset by increases in funding under the MPAR grant which began in September 2024.

Research & Development Expenses - R&D expenses were $3.6 million for the fourth quarter of 2025 compared to $3.8 million for the same period in 2024. Research and development expenses were $10.4 million for the year ended December 31, 2025, compared to $7.2 million for the year ended December 31, 2024, respectively, representing an increase of $3.2 million. The increase was primarily the result of external research and development costs related to increased clinical and pre-clinical programs for PF614 and PF614-MPAR.

General & Administrative Expenses - G&A expenses were $1.1 million in the fourth quarter of 2025, consistent with $1.1 million for the fourth quarter of 2024. For 2025, G&A expenses were $4.9 million, representing an increase of $0.2 million compared to $4.7 million for 2024.

Other Income (Expense) - Total other income (expense) was income of $13,856 for the fourth quarter of 2025 compared to income of $12,054 in the same period of 2024. For 2025, total other income (expense), net was income of $64,759 compared to expense of $1.3 million for 2024. Other income and expense for the year ended December 31, 2025, consisted primarily of interest income from cash and cash equivalents. Other income and expense for the year ended December 31, 2024, consisted primarily of interest expense associated with the amortization of the original issue discount and the debt issuance costs associated with convertible notes issued in 2023.

Net Income (Loss) - Net loss attributable to common stockholders for the fourth quarter of 2025 was $2.8 million compared to a net loss of $3.6 million for the fourth quarter of 2024. For 2025, net loss was $10.2 million compared to $8.0 million for 2024. 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 pharmaceutical company dedicated to disrupting the analgesic landscape through the development of a new class of safer opioid medicines for the treatment of severe pain. Leveraging its proprietary Trypsin-Activated Abuse Protection (TAAP™) and Multi-Pill Abuse Resistance (MPAR®) platforms, Ensysce is advancing tamper-resistant therapeutic options designed to minimize the risk of opioid abuse and oral overdose while preserving strong analgesic efficacy. For more information, 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, 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.

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

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Operations

	2021	2020	2021	2020
	Three Months Ended December 31,		Year Ended December 31,	
	2025	2024	2025	2024
Federal grants	$ 1,882,336	$ 1,303,659	$ 5,066,650	$ 5,210,031
Operating expenses:				
Research and development	3,613,029	3,802,630	10,376,895	7,219,437
General and administrative	1,051,132	1,077,505	4,930,701	4,720,728
Total operating expenses	4,664,161	4,880,135	15,307,596	11,940,165
Loss from operations	(2,781,825)	(3,576,476)	(10,240,946)	(6,730,134)
Total other income (expense), net	13,856	12,054	64,759	(1,256,875)
Net loss	$ (2,767,969)	$ (3,564,422)	$ (10,176,187)	$ (7,987,009)
Adjustments to net loss	321	-	487	(216)
Net loss attributable to common stockholders	$ (2,767,648)	$ (3,564,422)	$ (10,175,700)	$ (7,987,225)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.75)	$ (2.90)	$ (3.98)	$ (11.45)

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows

	2021	2020
	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (7,806,292)	$ (7,502,700)
Net cash used in investing activities	(123,643)	-
Net cash provided by financing activities	8,738,212	9,881,173
Change in cash and cash equivalents	808,277	2,378,473
Cash and cash equivalents at beginning of period	3,502,077	1,123,604
Cash and cash equivalents at end of period	$ 4,310,354	$ 3,502,077

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

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 4,310,354	$ 3,502,077
Prepaid expenses and other current assets	2,932,114	1,842,605
Total current assets	7,242,468	5,344,682
Property and equipment, net and other assets	210,011	252,550
Total assets	$ 7,452,479	$ 5,597,232
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,267,610	$ 1,357,079
Accrued expenses and other liabilities	993,411	548,458
Notes payable and accrued interest	306,708	301,660
Total current liabilities	4,567,729	2,207,197
Long-term liabilities	-	10,096
Total liabilities	4,567,729	2,217,293
Stockholders' equity	2,884,750	3,379,939
Total liabilities and stockholders' equity	$ 7,452,479	$ 5,597,232

SOURCE: Ensysce Biosciences, Inc.

View the original press release on ACCESS Newswire