November 14, 2025

Ensysce Biosciences Reports Third Quarter 2025 Financial Results

~ Third Quarter Highlighted by Initiation of Phase 3 Study of PF614, Underscoring Progress Toward Market Readiness and Commitment to Novel Opioid Solutions ~

~ Further Program Advancement Supported by Preferred Stock Financing ~

SAN DIEGO, CA / ACCESS Newswire / November 14, 2025 /Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or the "Company"), a clinical-stage pharmaceutical company pioneering next-generation severe pain therapeutics designed to minimize abuse and overdose risk, today reported financial and operational results for the third quarter ended September 30, 2025.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "It has been another highly productive quarter as we navigate tumultuous times in drug development. Our team continued meaningful progress throughout the third quarter as we advanced what we consider a new evolution in opioid therapeutics, focused on delivering safer, highly efficacious options for severe pain management using our innovative platforms." She continued, "The initiation of our pivotal Phase 3 PF614-301 trial in July marks a major milestone in our mission to transform pain management. This study is designed to demonstrate PF614's ability to provide effective pain relief while supporting safe transitions to non-opioid care. Our alliance with Rho, Inc. ensures rigorous execution as we work to unlock significant long-term value through innovation in opioid safety."

Dr. Kirkpatrick added, "We are also buoyed by encouragement from the U.S. Food and Drug Administration ("FDA") for our PF614-MPAR program, with Breakthrough Therapy designation, including working to align on overdose protection labeling and a regulatory pathway forward. This milestone reinforces our mission and commitment to transform opioid safety through scientific innovation, and we are proud to be working collaboratively with the FDA to ensure the full benefits of our technology reach the patients for which they are intended."

"Looking ahead, we believe Ensysce is positioned to launch the next-generation opioid analgesia. Our strategy integrates scientific rigor, responsible development, and continued collaboration with National Institute on Drug Abuse ("NIDA") and FDA to address the dual challenges of pain and abuse. Our current investors have continued to support this development path through a convertible preferred stock financing and we appreciate the opportunity to move forward with our programs buoyed by their commitment to our mission. Each milestone brings us closer to redefining how severe pain can be treated - with efficacy, safety, and accountability at the core." Dr. Kirkpatrick concluded.

TAAP™ (Opioid Abuse Deterrent Program) Update

The Company's lead product, PF614, is a Trypsin-Activated Abuse Protection (TAAP™) extended-release oxycodone and a potential "next generation" analgesic to treat severe pain. PF614's TAAP™ chemical modification of oxycodone renders it inactive until it is swallowed and exposed to the body's own trypsin in the small intestine to activate or "switch on" to release oxycodone. The TAAP™ technology is designed to control release when administered orally, be highly resistant to tampering, and reduce abuse, with a goal of providing what the Company believes is a safer opioid product for those suffering from severe pain who require opioid-strength analgesia.

In July, Ensysce announced the initiation of its pivotal PF614-301 clinical trial, designed to evaluate the efficacy of PF614 in managing moderate to severe post-surgical pain following abdominoplasty. The study seeks to validate PF614's ability to deliver effective pain relief while reducing the risk of opioid abuse and supporting a safer transition to non-opioid outpatient care. To conduct the trial, Ensysce engaged Rho, Inc., a clinical research organization with extensive experience in central nervous system ("CNS") and pain-related studies. This initiation of services represents a significant milestone in Ensysce's mission to introduce a safer class of opioids and transform the future of pain management.

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

PF614-MPAR is a combination product of the TAAP™ and MPAR® (Multi-Pill Abuse Resistance) technology to treat severe pain with the added benefit of oral overdose protection. PF614-MPAR combines prodrug PF614 with a trypsin inhibitor to reduce or "switch off" the release of the opioid in an overdose situation. Data from the initial clinical trial PF614-MPAR-101, demonstrating that the MPAR® technology worked as designed to provide the desired overdose protection to PF614-MPAR at a 25 mg dose, led to the FDA's Breakthrough Therapy designation in January 2024.

In July, Ensysce received encouraging feedback from the FDA regarding the development of PF614-MPAR. The FDA supported Ensysce's pursuit of overdose protection labeling and confirmed the potential for a streamlined 505(b)(2) regulatory pathway, which could accelerate market entry. PF614-MPAR is engineered to activate overdose protection automatically when doses exceed prescribed limits. The FDA and Ensysce are aligned on a collaborative approach to ensure the drug's full safety benefits are recognized, including the creation of a whitepaper on overdose protection. This milestone, backed by multi-year NIDA grants, marks a significant step toward transforming opioid safety and redefining pain management.

Opioid Use Disorder (OUD) Program Update

In addition to its pain management pipeline, Ensysce is advancing innovative treatments for opioid use disorder (OUD), including novel compounds designed to reduce cravings and prevent relapse without compromising quality of life. Leveraging its proprietary TAAP™ and MPAR® technologies, the Company is developing what may be a safer methadone alternative. In 2024, Ensysce selected PF9001 as its lead OUD candidate, evaluating it for oral delivery, reduced cardiovascular risk, and built-in overdose protection. Supported by a multi-year HEAL (Helping to End Addiction Long-Term) grant, with encouragement from NIDA, the program is progressing toward non-clinical studies to support a future Investigational New Drug (IND) application.

Q3 2025 Financial Results

Cash - Cash and cash equivalents were $1.7 million as of September 30, 2025, compared to $3.5 million as of December 31, 2024. In November 2025, the Company completed a convertible preferred stock offering with gross proceeds of $4 million, with potentially $16 million of additional funding available through future tranches over the next 24 months.

Federal Grants - Funding under federal grants totaled $0.5 million for the third quarter of 2025, compared to $3.4 million in the same quarter of 2024. The $2.9 million decrease is primarily due to the timing of research activities eligible for funding under the MPAR grant which began in September 2024. The 2024 period included significant funding under the OUD grant with research activity following the selection of a lead product candidate in June 2024.

Research & Development Expenses - R&D expenses were $3.0 million for the third quarter of 2025 compared to $1.7 million for the same period in 2024. The increase was primarily the result of external research and development costs related to increased clinical and pre-clinical activity for PF614 and PF614-MPAR in the 2025 period.

General & Administrative Expenses - G&A expenses were $1.3 million for the third quarter of 2025, relatively in line with $1.1 million during the same year ago period.

Other Income (Expense) - Total other income (expense) was income of $11,967 for the third quarter of 2025 compared to income of $17,023 in the same period of 2024.

Net Income (Loss) - Net loss attributable to common stockholders for the third quarter of 2025 was $3.7 million compared to a gain of $0.7 million for the third quarter of 2024. As a clinical-stage biotech company, the Company's continued research and development efforts toward regulatory approvals for its 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; 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 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. 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Federal grants	$ 493,104	$ 3,418,853	$ 3,184,314	$ 3,906,372
Operating expenses:				
Research and development	2,954,909	1,690,674	6,763,866	3,416,807
General and administrative	1,279,290	1,083,433	3,879,569	3,643,223
Total operating expenses	4,234,199	2,774,107	10,643,435	7,060,030
Income (loss) from operations	(3,741,095)	644,746	(7,459,121)	(3,153,658)
Total other income (expense), net	11,967	17,023	50,903	(1,268,929)
Net income (loss)	$ (3,729,128)	$ 661,769	$ (7,408,218)	$ (4,422,587)
Adjustments to net income (loss)	-	-	166	(216)
Net income (loss) attributable to common stockholders	$ (3,729,128)	$ 661,769	$ (7,408,052)	$ (4,422,803)
Net income (loss) per share attributable to common stockholders, basic and diluted	$ (1.29)	$ 1.00	$ (3.42)	$ (8.52)

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

	Nine Months Ended September 30,	
	2025	2024
Net cash used in operating activities	$ (6,280,459)	$ (6,738,610)
Net cash used in investing activities	(123,643)	-
Net cash provided by financing activities	4,575,243	9,768,598
Change in cash and cash equivalents	(1,828,859)	3,029,988
Cash and cash equivalents at beginning of period	3,502,077	1,123,604
Cash and cash equivalents at end of period	$ 1,673,218	$ 4,153,592

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

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 1,673,218	$ 3,502,077
Prepaid expenses and other current assets	1,255,052	1,842,605
Total current assets	2,928,270	5,344,682
Other assets	251,194	252,550
Total assets	$ 3,179,464	$ 5,597,232
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 463,458	$ 1,357,079
Accrued expenses and other liabilities	1,453,555	548,458
Notes payable and accrued interest	387,702	301,660
Total current liabilities	2,304,715	2,207,197
Long-term liabilities	35	10,096
Total liabilities	2,304,750	2,217,293
Stockholders' equity	874,714	3,379,939
Total liabilities and stockholders' equity	$ 3,179,464	$ 5,597,232

SOURCE: Ensysce Biosciences

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