November 13, 2026

Zacks Small-Cap Research

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Brad Sorensen
312-265-9574
bsorensen@zacks.com

scr.zacks.com
101 N. Wacker Drive, Chicago, IL 60606

Ensysce Biosciences (ENSC-NASDAQ)

ENSC: Transformational Quarter for Company

ENSC is a clinical stage pharmaceutical company dedicated to bringing a novel opioid to the market that resists the addictive properties that have plagued society.

OUTLOOK

Ensysce Biosciences is committed to finding a solution to the opioid crisis plaguing the US and other developed countries around the world. Through its proprietary TAAP technology Ensysce is in the process of receiving approval for an abuse-resistant yet still pain-relieving opioid.

The company had a transformational 3Q2026. ENSC acquired CY Biopharma, which gave them another promising treatment for chronic pain.

Current Price (11/12/26)	$0.39
Valuation	**$8.25**

SUMMARY DATA

52-Week High	**$2.57**
52-Week Low	**$0.25**
One-Year Return (%)	**-81.29**
Beta	**1.11**
Average Daily Volume (sh)	**299,966**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$8**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
Insider Ownership (%)	**3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	0.8A	0.5A	0.4A	0.5A	2.2A
2024	0.3A	0.2A	3.4A	1.3A	5.2A
2025	1.3A	1.4A	0.5A	1.9A	5.1A
2026	1.0A	1.2A	2.2A	2.2E	6.6E

Earnings per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-2.08A	-0.98A	-0.87A	-1.13A	-5.06A
2024	-0.55A	-0.22A	0.07A	-2.90A	-11.45A
2025	-1.39A	-0.79A	-1.29A	-0.75A	-3.98A
2026	-0.52A	-0.20A	-4.52 E	-0.14E	-5.38E

*quarters don't add to yearly total due to reverse stock split and share issuance.

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Update

Ensysce Biosciences (ENSC) delivered a promising third-quarter 2026 business update that highlights the company's transformation into a more diversified biotechnology developer with multiple promising approaches to treating severe pain. The release demonstrates to us and to investors meaningful progress across its clinical pipeline, particularly the advancement of its recently acquired CY200 program targeting Complex Regional Pain Syndrome (CRPS), as well as continued development of its innovative opioid abuse-deterrent and overdose-protection technologies. Importantly, these advancements are supported by a substantially strengthened balance sheet, providing Ensysce with greater financial flexibility to pursue important clinical and regulatory milestones.

Ensysce is a clinical-stage biotechnology company focused on developing safer and potentially more effective treatments for pain. Historically, the company's development efforts centered on its proprietary Trypsin-Activated Abuse Protection (TAAP) and Multi-Pill Abuse Resistance (MPAR) technologies, designed to maintain the pain-relieving benefits of opioid medications while reducing the potential for abuse and overdose. However, the August 2026 acquisition of Cy Biopharma significantly expanded Ensysce's therapeutic strategy, adding an innovative neuroplastogenic treatment for CRPS and creating a second, differentiated avenue for addressing serious unmet medical needs.

The significance of the third-quarter update to us is that Ensysce now has three important clinical development opportunities, each addressing a different aspect of pain treatment and potentially offering substantial value if successfully developed and approved.

CY200: A New Lead Program Targeting a Serious Unmet Medical Need

We believe the most important development during the quarter was the acquisition of Cy Biopharma and its lead drug candidate, CY200. The treatment is being developed for Complex Regional Pain Syndrome, a severe and frequently debilitating chronic pain condition that can develop following an injury or surgical procedure. CRPS can cause persistent pain, extreme sensitivity to touch, swelling, and changes in skin temperature and mobility, often dramatically reducing patients' quality of life. Treatment options for CRPS remain limited, and there are currently no FDA-approved medications specifically indicated for the condition. Existing approaches frequently involve combinations of pain medications, physical therapy, and other interventions, with inconsistent results. This creates a potentially attractive opportunity for an effective new treatment that could address the condition's underlying neurological dysfunction rather than simply suppress its symptoms.

CY200 is a psilocybin-predominant botanical extract being developed as a neuroplastogenic therapy. Neuroplastogenic treatments are intended to promote neuroplasticity, the brain and nervous system's ability to reorganize and modify neural connections. The scientific rationale is that abnormal pain signaling and changes in the central nervous system may contribute to the persistence of CRPS. By potentially modifying these dysfunctional neural pathways, CY200 could offer benefits beyond those associated with conventional pain-relieving medications.

The program builds upon an observational pilot study involving psilocybin in patients with CRPS and other chronic pain conditions. Although this preliminary research provides a basis for further investigation, it does not establish clinical efficacy, making the upcoming controlled study particularly important.

During September, Ensysce submitted the protocol for its planned Phase 2a CYBIO 001 trial to the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA). The study is designed as a multicenter, randomized, double-blind, placebo-controlled trial evaluating CY200 in adults with CRPS Type 1. This design is important because it should provide more rigorous evidence of safety, tolerability, and potential effectiveness than earlier observational findings.

On November 6, the MHRA and the relevant research ethics committee requested additional information regarding the clinical trial application. Ensysce is preparing its response, with the objective of securing clearance and initiating patient enrollment. While this represents an additional regulatory step, rather than an approved trial ready to enroll, management continues preparing clinical sites and personnel to advance the program once authorization is received.
Another valuable feature of CY200 that we don't think investors should overlook is that its active ingredient has received FDA Orphan Drug Designation for CRPS. This designation provides development incentives, including potential tax benefits and seven years of U.S. market exclusivity following approval, provided applicable requirements are met.

Ensysce also increased the program's scientific visibility during the quarter, hosting a CRPS-focused symposium at PainWeek 2026 and participating in discussions surrounding the future therapeutic use of psychedelic medicines. We believe these initiatives could help strengthen relationships with clinicians and researchers as the company advances its development strategy.

PF614-MPAR: Advancing a Potentially Breakthrough Approach to Opioid Safety

Alongside CY200, Ensysce continues making progress with PF614-MPAR, one of its most differentiated drug development programs. PF614-MPAR combines the company's TAAP technology with its proprietary MPAR system to create an extended-release opioid treatment engineered to reduce the risk of overdose from excessive oral consumption.

PF614 is designed to remain inactive until it reaches the small intestine, where the digestive enzyme trypsin activates the medication, allowing oxycodone to be released. The addition of MPAR technology is intended to limit the amount of active opioid released when multiple doses are taken, potentially reducing the danger associated with intentional or accidental overconsumption.
This approach addresses a significant limitation of traditional opioid abuse-deterrent technologies. While certain existing products are designed to make crushing, injecting, or snorting opioids more difficult, they do not necessarily protect patients against consuming excessive numbers of pills. Ensysce's MPAR technology seeks to address this additional and potentially life-threatening source of risk.

The FDA has granted PF614-MPAR Breakthrough Therapy Designation, an important regulatory recognition intended to facilitate development and potentially expedite review of treatments for serious conditions when preliminary clinical evidence indicates substantial improvement over available therapies on clinically significant endpoints. Although this designation does not guarantee approval, it creates opportunities for more intensive FDA interaction and a potentially more efficient regulatory development process.

We believe a significant milestone was achieved in August 2026 when Ensysce completed enrollment in Part 3, the final stage of its PF614-MPAR-102 clinical study. This stage is designed to evaluate the treatment's protective characteristics across a range of dosing conditions while also examining how food affects the release of the active medication and its intended overdose-protection properties.

The completion of enrollment represents meaningful progress toward generating the clinical evidence necessary to support further development. Results from this stage, together with remaining nonclinical studies and regulatory discussions, will help determine the path toward a potential New Drug Application.

Importantly, the MPAR program continues to benefit from financial support through a $15.1 million multiyear award from the National Institute on Drug Abuse (NIDA). As of September 30, approximately $2.7 million remained available under the award to support completion of the study and additional long-term nonclinical work. This outside funding helps reduce the amount of corporate capital required to advance the program.

The investment potential of PF614-MPAR remains significant in our view. Opioid medications continue to play an important role in treating severe pain, despite the risks associated with their use. A product that could preserve effective pain relief while offering clinically demonstrated protection against certain forms of overdose could represent a meaningful advance in pain management and potentially attract commercial or strategic partnering interest. However, the extent of that protection, its clinical relevance, and any eventual labeling claims remain subject to regulatory review and successful testing.

PF614: Continuing Development of a Safer Extended-Release Opioid

Ensysce's third major development program, PF614, also continues progressing through late-stage clinical testing. PF614 utilizes the company's TAAP technology to create an extended-release oxycodone formulation designed to resist common methods of opioid abuse.

Unlike conventional oxycodone formulations, PF614 is designed to require activation by trypsin in the small intestine before releasing its active ingredient. This creates a potential barrier against non-oral abuse methods, particularly crushing and snorting or injecting the medication. If the technology performs as intended in clinical use, it could provide physicians with another option for treating moderate to severe pain while reducing certain risks associated with opioid misuse.

The program is currently in the pivotal PF614-301 Phase 3 trial, a multicenter, randomized, double-blind, placebo-controlled study evaluating the treatment for moderate to severe pain following abdominoplasty, a surgical procedure involving the abdomen. This study is intended to provide important evidence of PF614's analgesic efficacy and safety.

For shareholders, these programs offer multiple opportunities for clinical progress and potential partnerships, while giving Ensysce a broader portfolio of differentiated pain treatments.

Financial Results: Substantially Improved Liquidity Supports the Pipeline

Ensysce's third-quarter financial results were highlighted by a dramatic improvement in its cash position, reflecting both new financing and the acquisition of Cy Biopharma.
The company ended September 30, 2026, with approximately $29.7 million in cash and cash equivalents, compared with $4.3 million at the end of 2025. This strengthening resulted primarily from $21.1 million in net cash generated through financing activities, including $19.6 million in net proceeds from its Series C private placement, as well as approximately $11.4 million in cash acquired through the Cy Biopharma transaction.

This increased liquidity is especially significant given Ensysce's expanded clinical pipeline. It provides resources to prioritize the CY200 Phase 2a program while continuing development of its opioid safety technologies. The company used approximately $6.9 million in operating cash during the first nine months of 2026, although future spending could increase as the CY200 clinical program advances.

Research and development expenses increased modestly to approximately $3.2 million during the quarter, compared with $3.0 million a year earlier, while general and administrative expenses increased to $1.6 million from $1.3 million. Both increases were influenced by the Cy Biopharma acquisition.

Federal grant funding increased substantially to $2.2 million from approximately $493,000 in the comparable 2025 quarter, reflecting increased eligible research activity under the MPAR program. Ensysce reported a net loss attributable to common shareholders of approximately $82.3 million, compared with a loss of $3.7 million a year earlier. Although the headline increase appears substantial, approximately $79.9 million of the latest quarterly loss resulted from a one-time, noncash accounting charge associated with acquired in-process research and development related primarily to CY200. Excluding this acquisition-related accounting charge, the reported loss would have been approximately $2.4 million.

We believe the important financial takeaway for investors is that Ensysce enters its next stage of clinical development with a significantly stronger balance sheet and greater access to capital than it had at the beginning of the year. While additional financing may ultimately be necessary to fund later-stage trials and commercialization, its current liquidity provides greater flexibility to pursue its near-term objectives.

Investment Outlook: Multiple Potential Catalysts and an Expanding Opportunity

We are encouraged that the third quarter of 2026 represents a meaningful turning point for Ensysce Biosciences. Through the addition of CY200, continued advancement of PF614-MPAR, and ongoing Phase 3 development of PF614, the company has assembled a diversified portfolio of pain therapeutics addressing important medical needs through distinctly different mechanisms.

The most immediate catalyst is the regulatory clearance and initiation of the CY200 Phase 2a study. Successful execution of this trial would begin generating controlled clinical evidence supporting the treatment's potential in CRPS, a serious condition without an FDA-approved therapy specifically indicated for it. Positive results could substantially strengthen the program's attractiveness to potential pharmaceutical partners and investors.

Additional catalysts include the release and interpretation of data from PF614-MPAR-102, subsequent FDA interactions regarding its Breakthrough Therapy development pathway, and progress in the pivotal PF614 Phase 3 program. Each provides a separate opportunity for Ensysce to demonstrate the clinical relevance of its technologies and potentially increase the value of its drug development portfolio.

The company's strengthened financial position adds to our positive outlook. With nearly $30 million in cash at quarter-end, Ensysce has greater flexibility to advance its lead program and evaluate strategic opportunities without the same immediate financial constraints that previously characterized its development efforts.

The principal risks remain clinical execution, regulatory uncertainty, future financing requirements, and the inherent difficulty of bringing innovative therapies to market. In particular, CY200 must still clear its pending UK regulatory review and demonstrate efficacy in controlled studies, while the opioid programs must successfully complete the testing necessary to support approval.

Nevertheless, Ensysce's third-quarter update provides substantial evidence of an improving investment proposition. The company now combines a promising new neuroplastogenic treatment opportunity with two advanced opioid-safety programs, supported by a substantially improved balance sheet. Management's focus on moving CY200 into Phase 2a testing while advancing its established pipeline creates multiple potential value-driving events over the coming clinical development cycle.

For investors willing to accept the risks associated with clinical-stage biotechnology, Ensysce offers an intriguing opportunity to participate in the development of differentiated pain therapeutics. The progress achieved during the third quarter strengthens the argument that the company is entering a

more consequential stage of its development, with multiple opportunities to translate its scientific innovations into clinically and commercially valuable treatments.

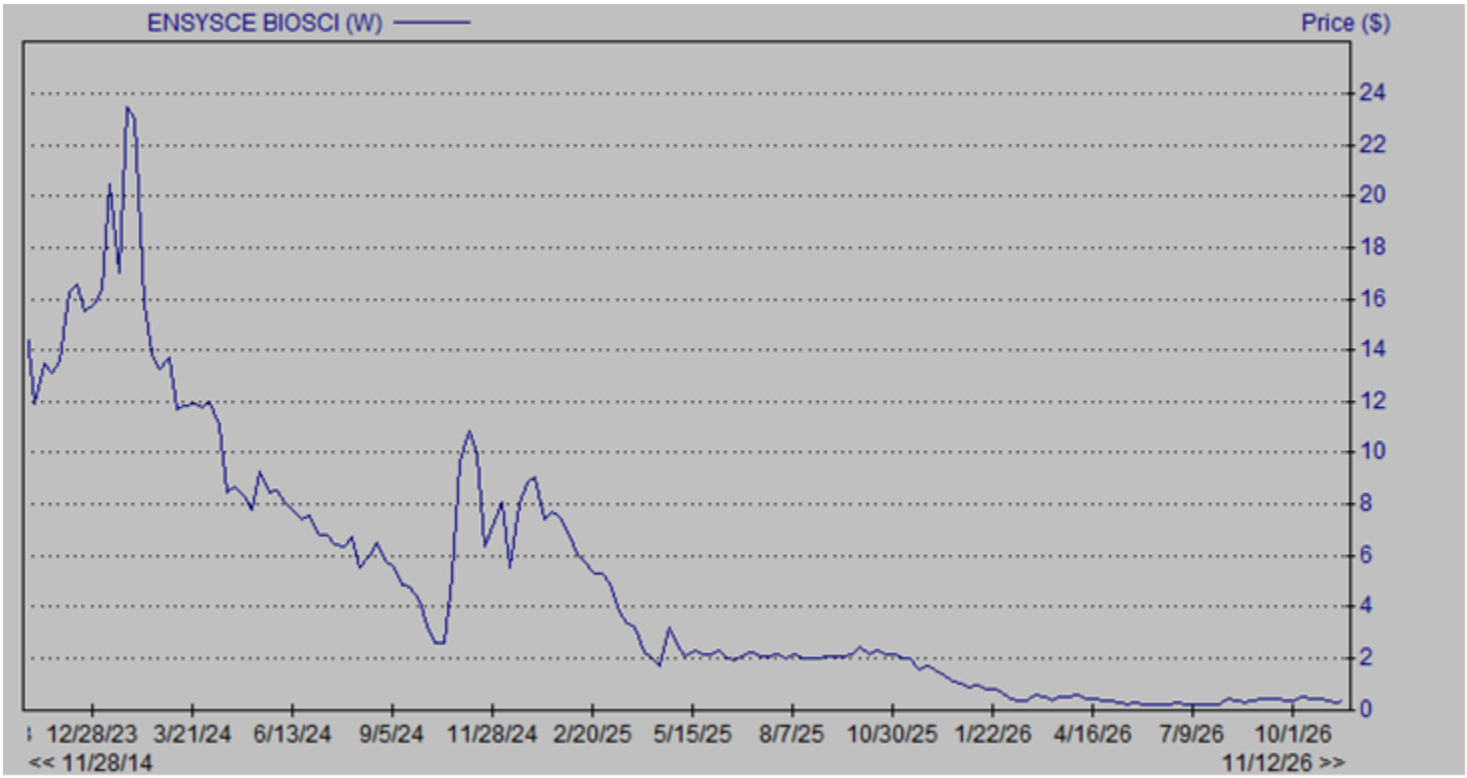
PROJECTED INCOME STATEMENT & BALANCE SHEET

Ensysce Biosciences

Income Statement and Balance Sheet

		1Q/2025A	2Q/2025A	3Q/2025A	4Q/2025A	1Q/2026A	2Q/2026A	3Q/2026A	4Q/2026E	12/2027E
Income										
	Federal Grants	1,319,772	1,371,438	493,104	1,882,336	960,999	1,164,315	2,181,632	2,203,448	0
	Sales	0	0	0	0	0	0	0	0	2,500,000
Operating Expenses										
	COGS	0	0	0	0	0	0	0	0	(250,000)
	R&D	(1,885,528)	(1,923,430)	(2,954,909)	(3,613,029)	(3,346,881)	(2,471,752)	(3,175,848)	(3,239,365)	(1,979,804)
Other	Sales/Marketing	0	0	0	0	0	0	0	0	(250,000)
	Admin/general/other	(1,379,817)	(1,178,365)	(1,279,290)	(1,037,276)	(1,176,348)	(1,268,952)	(1,594,722)	(1,594,723)	(1,448,808)
	Interest and other expenses	(3,856)	(3,160)	0	0	(3,923)	0	382,578	401,707	(15,424)
	Acquired in-process r&d	0	0	11,967	321	9,738	5,514	(79,907,223)	0	0
Gain/loss		(1,945,573)	(1,733,517)	(3,729,128)	(2,767,648)	(3,556,415)	(2,570,875)	(82,113,583)	(2,630,640)	(928,612)
Loss attributable to noncontrolling		0	(166)	0	0	0	(166)	(82,113,583)	0	0
Deemed div. rel.to warrants		0	0	0	0	0	0	0	0	0
Net Loss Attr. to Common S/H		(1,945,573)	(1,733,351)	(3,729,128)	(2,767,648)	(3,556,415)	(2,570,709)	(82,318,122)	(2,630,640)	(928,612)
Shares		1,401,144	2,202,299	2,890,797	3,690,197	6,839,385	13,035,632	18,193,164	19,102,822	20,057,963
Per share		($1.39)	($0.79)	($1.29)	($0.75)	($0.52)	($0.20)	($4.52)	($0.14)	($0.05)
Assets										
	Cash	3,052,491	2,211,575	1,673,218	4,310,354	745,482	676,704	29,670,793	14,835,397	13,351,857
	Other	1,559,383	3,362,880	1,506,246	3,142,125	1,422,321	2,280,569	1,282,588	1,346,717	1,414,053
Total Assets		4,611,874	5,574,455	3,179,464	7,452,479	2,167,803	2,957,273	30,953,381	16,182,114	14,765,910
Liabilities										
	Accounts Payable	615,295	1,042,832	463,458	3,267,610	1,610,186	1,977,629	2,033,669	2,074,342	2,115,829
	Other liabilities	1,145,881	1,470,178	1,841,257	1,300,119	1,226,629	2,090,477	1,807,934	1,862,172	1,918,037
Long-term liabilities		130,180	1,033	35	0	0	0	0	0	0
Total liabilities		1,891,356	2,514,043	2,304,750	4,567,729	2,836,815	4,068,106	3,841,603	3,936,514	4,033,866
Shareholder deficit/surplus		2,720,518	3,060,412	874,714	2,884,750	(669,012)	(1,110,833)	27,111,778	12,245,600	10,732,044
Total liabilities and shareholder equity		4,611,874	5,574,455	3,179,464	7,452,479	2,167,803	2,957,273	30,953,381	16,182,114	14,765,910

HISTORICAL STOCK PRICE



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