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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: Entering Pivotal Stage in Good Shape

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

Ensyesce 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 Ensyesce is in the process of receiving approval for an abuse-resistant yet still pain-relieving opioid.

The company announced its 2Q financial results and showed that ENSC is in solid fiscal shape heading into a critical period.

Current Price (08/13/26) \$0.35
Valuation \$8.25

SUMMARY DATA

52-Week High \$2.57
52-Week Low \$0.25
One-Year Return (%) -83.08
Beta 0.84
Average Daily Volume (sh) 42,097,140

Shares Outstanding (mil) 15
Market Capitalization (\$mil) \$5
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	1.2E	1.2E	4.6E

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	-0.19 E	-0.18E	-1.09E

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

Update

Ensysce Biosciences is entering what may be the most consequential period in its history. The clinical-stage biotechnology company has spent years developing technologies intended to make powerful pain medications safer, but the recently completed acquisition of Cy Biopharma materially changes the investment story. Ensysce now combines its advanced opioid programs—including a Phase 3 candidate and an FDA Breakthrough Therapy-designated overdose-protection program—with CY200, a clinical-stage neuroplastogenic treatment for Complex Regional Pain Syndrome (CRPS). Just as importantly, the transaction was accompanied by substantial financing that dramatically improves the company's ability to advance its enlarged pipeline.

A Broader and More Advanced Pipeline

The centerpiece of the newly expanded pipeline is **CY200**, acquired through the August 6 acquisition of Cy Biopharma. CY200 is being developed for CRPS Type 1, a debilitating chronic pain condition for which Ensysce notes there is currently no approved therapy. Unlike conventional pain treatments that primarily attempt to control symptoms, CY200 uses a neuroplastogenic approach intended to address the underlying neurobiology associated with the disease. The FDA has already granted CY200 Orphan Drug Designation, providing regulatory and potential commercial advantages if development is successful.

Ensysce plans to advance CY200 through a randomized Phase 2 study evaluating efficacy, safety and tolerability in CRPS Type 1 patients. Management estimates the relevant pain market at more than \$1 billion and expects the newly raised capital to fund CY200 through Phase 2 proof-of-concept data and preparations for registrational development. This creates an important potential value inflection point: compelling Phase 2 efficacy data in a severe disorder with no approved therapy could substantially change how investors value the program.

Importantly, CY200 does not replace Ensysce's existing opioid programs. Instead, it adds a second major technology platform and gives the company several independent opportunities for clinical success.

The company's original lead program, PF614, is an extended-release oxycodone prodrug built around Ensysce's Trypsin-Activated Abuse Protection, or TAAP™, technology. PF614 remains inactive until swallowed and exposed to trypsin in the small intestine, where it is converted to release oxycodone. This design is intended to make common forms of manipulation and abuse more difficult while still providing effective opioid pain relief. PF614 is currently being evaluated in the pivotal PF614-301 Phase 3 trial, a randomized, double-blind, placebo-controlled study in patients experiencing moderate-to-severe pain following abdominoplasty.

The next-generation PF614-MPAR program could ultimately be even more differentiated. It combines TAAP with Ensysce's Multi-Pill Abuse Resistance, or MPAR®, technology, which is designed not only to deter abuse but also to limit opioid exposure when excessive numbers of pills are consumed. In effect, Ensysce is attempting to engineer overdose protection directly into an opioid medication. PF614-MPAR has received FDA Breakthrough Therapy designation, an important regulatory validation of the potential significance of the technology. Enrollment is continuing in the PF614-MPAR-102 clinical study.

The federal government has also provided meaningful external support. During the quarter, Ensysce secured the third year of funding under its \$15.1 million National Institute on Drug Abuse grant, completing the multi-year award. As of June 30, approximately \$5.3 million remained available through May 2027. Ensysce notes that NIDA has now supported the program with two major awards totaling more than \$26 million over six years, reducing the amount of shareholder capital required to fund portions of the MPAR program.

Beyond these clinical-stage pain programs, Ensysce has demonstrated that its underlying technology can potentially be expanded into additional large therapeutic markets. Its ADHD pipeline includes PF8026, an immediate-release amphetamine prodrug, and PF8001, an extended-release candidate. The objective is to apply TAAP and eventually MPAR principles to stimulant medications, potentially creating ADHD treatments with abuse-deterrent and overdose-protection characteristics. The company is also developing PF9001 for opioid use disorder (OUD), envisioned as a next-generation alternative to methadone with overdose protection and potentially reduced cardiovascular risk.

That creates a uniquely broad opportunity for a company of Ensysce's size: CY200 in CRPS, PF614 in severe pain, PF614-MPAR for pain with overdose protection, PF8026/PF8001 in ADHD and PF9001 in opioid use disorder.

Cy Biopharma Acquisition Transforms the Financial Picture

The Cy Biopharma transaction is significant not simply because it adds CY200. The accompanying financing substantially changes Ensysce's balance-sheet outlook.

Ensysce acquired Cy Biopharma in a stock-for-stock transaction. Cy brought approximately \$17.1 million of cash from a pre-acquisition convertible-note financing. At the same time, Ensysce arranged approximately \$21.5 million of gross proceeds through the sale of Series C non-voting convertible preferred stock. A second financing tranche of up to \$38.6 million can be triggered upon achievement of specified clinical milestones. Altogether, the transaction and associated financings potentially provide approximately \$77 million of capital.

The quality of the financing syndicate is also notable to us. The private placement was led by Ally Bridge Group and included Perceptive Advisors, Dellora Investments, Ikarian Capital and Adage Capital Partners. Participation from healthcare-focused institutional investors provides an additional measure of validation for both the transaction and the clinical opportunity being pursued.

Additionally, Ensysce said it received approximately \$31 million of cash net of transaction expenses, extending its expected cash runway into late 2027. If the additional \$38.6 million milestone-based tranche is funded, management believes its runway could extend into 2028.

Financing risk has historically been one of the largest concerns surrounding small clinical-stage biotechnology companies such as Ensysce. The Cy transaction simultaneously adds what management now considers its lead clinical asset and gives the company substantially greater financial resources to develop it.

Second-Quarter Results Reflect Increasing Clinical Investment

The second-quarter results released August 13 need to be viewed in that context because the June 30 balance sheet predates the Cy acquisition and associated financing.

Ensysce ended June with approximately \$677,000 in cash, versus \$4.3 million at year-end 2025, after using approximately \$5.5 million of cash in operations during the first six months. However, the approximately \$31 million of net cash added after quarter-end dramatically alters that snapshot.

Federal grant funding totaled approximately \$1.16 million during Q2, compared with \$1.37 million a year earlier, with the difference primarily reflecting the timing of reimbursable research activity. R&D expense increased to approximately \$2.47 million from \$1.92 million, largely because of increased clinical activity surrounding PF614. For a development-stage biotechnology company, the higher R&D spending can be viewed positively because it reflects acceleration of programs rather than deterioration in an established commercial operation.

G&A expense remained relatively controlled at approximately \$1.27 million, compared with \$1.20 million a year ago. Ensysce recorded a quarterly net loss attributable to common shareholders of approximately \$2.57 million, versus \$1.73 million in Q2 2025. The larger loss largely accompanies the company's increased investment in clinical development, which we view as a positive development.

One particularly positive financial takeaway is the contrast between Ensysce's operating expenditure and its post-quarter financing. The company spent roughly \$5.5 million on operations during the first six months of 2026, while the Cy transaction and financing subsequently generated approximately \$31 million of net cash, before considering the potential additional \$38.6 million milestone tranche or the remaining \$5.3 million of NIDA grant funding. That provides considerably more flexibility than Ensysce possessed only a few months ago.

Investment Outlook

The investment case for Ensysce has become substantially more interesting in our view following the Cy Biopharma acquisition. Previously, investors were primarily betting on whether Ensysce's TAAP and MPAR technologies could establish a new category of safer opioids. That opportunity remains intact, with PF614 already in pivotal Phase 3 development and PF614-MPAR carrying FDA Breakthrough Therapy designation.

Investors now receive an additional clinical opportunity through CY200 and CRPS. The combination creates two fundamentally different approaches to pain: a neuroplastogenic therapy intended to address the underlying biology of complex chronic pain and an advanced opioid platform engineered to reduce abuse and overdose.

Ensysce now appears better financed to reach the clinical milestones that could establish the value of those technologies. The approximately \$31 million of post-quarter net cash, potential additional \$38.6 million financing tranche and remaining NIDA support significantly reduce near-term funding pressure compared with the company's position entering 2026.

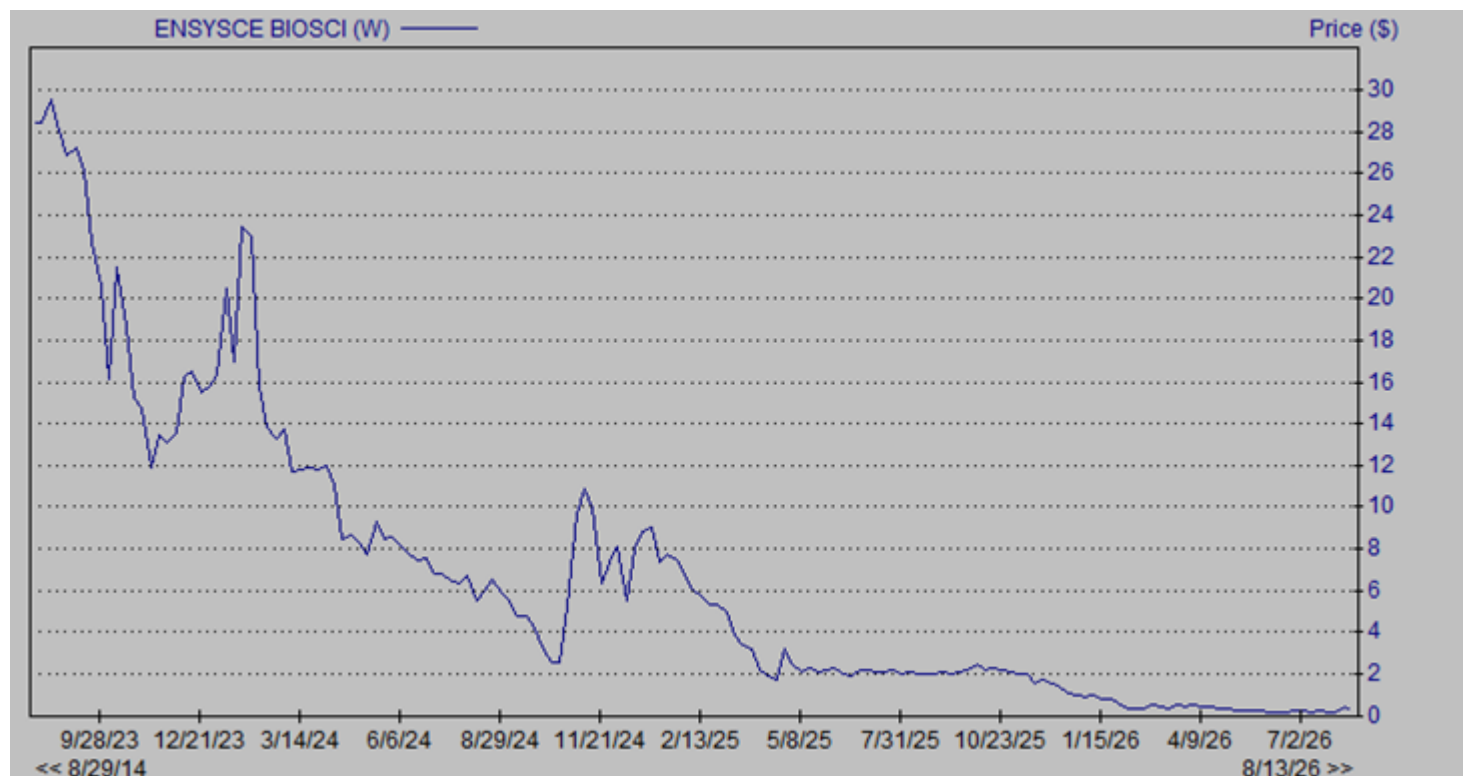
Ensysce remains a clinical-stage company with no approved products, continuing operating losses and meaningful potential dilution associated with equity financing. Clinical results—particularly from CY200, PF614 and PF614-MPAR—will ultimately determine the company's value.

Nevertheless, in our view the risk/reward profile has improved. Ensysce now possesses a diversified clinical pipeline, a Phase 3 pain asset, an FDA Breakthrough Therapy-designated overdose-protection program, an Orphan Drug-designated CRPS program and earlier-stage opportunities in ADHD and opioid use disorder. At the same time, the Cy Biopharma transaction has provided the financial runway needed to pursue several important clinical catalysts, leading us to suggest investors with a higher risk tolerance take a look at ENSC.

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/2026E	4Q/2026E	12/2027E
Income										
	Federal Grants	1,319,772	1,371,438	493,104	1,882,336	960,999	1,164,315	1,175,958	1,187,718	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)	(2,521,187)	(2,571,611)	(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)	(1,268,953)	(1,268,954)	(1,448,808)
	Interest	(3,856)	(3,160)	0	0	(3,923)	0	0	0	(15,424)
	Adjustments to net income	0	0	11,967	321	9,738	5,514	0	0	0
Gain/loss		(1,945,573)	(1,733,517)	(3,729,128)	(2,767,648)	(3,556,415)	(2,570,875)	(2,614,182)	(2,652,847)	(928,612)
Loss attributable to noncontrolling		0	(166)	0	0	0	(166)	0	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)	(2,614,182)	(2,652,847)	(928,612)
Shares		1,401,144	2,202,299	2,890,797	3,690,197	6,839,385	13,035,632	13,687,414	14,371,784	15,090,373
Per share		(\$1.39)	(\$0.79)	(\$1.29)	(\$0.75)	(\$0.52)	(\$0.20)	(\$0.19)	(\$0.18)	(\$0.06)
Assets										
	Cash	3,052,491	2,211,575	1,673,218	4,310,354	745,482	676,704	21,609,034	10,804,517	9,724,065
	Other	1,559,383	3,362,880	1,506,246	3,142,125	1,422,321	2,280,569	2,394,597	2,514,327	2,640,044
Total Assets		4,611,874	5,574,455	3,179,464	7,452,479	2,167,803	2,957,273	24,003,631	13,318,844	12,364,109
Liabilities										
	Accounts Payable	615,295	1,042,832	463,458	3,267,610	1,610,186	1,977,629	2,017,182	2,057,525	2,098,676
	Other liabilities	1,145,881	1,470,178	1,841,257	1,300,119	1,226,629	2,090,477	2,153,191	2,217,787	2,284,321
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	4,170,373	4,275,312	4,382,996
Shareholder deficit/surplus		2,720,518	3,060,412	874,714	2,884,750	(669,012)	(1,110,833)	19,833,258	9,043,532	7,981,112
Total liabilities and shareholder equity		4,611,874	5,574,455	3,179,464	7,452,479	2,167,803	2,957,273	24,003,631	13,318,844	12,364,109

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