

Zacks Small-Cap Research

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Ensysce Biosciences

(ENSC-NASDAQ)

ENSC: Expanding Global Footprint for Game Changing Treatments

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 that it has received patents for its treatments with built-in abuse and overdose protection, expanding its reach and potential commercialization opportunities.

Current Price (01/20/26) \$0.94
Valuation \$16.45

SUMMARY DATA

52-Week High \$8.28
52-Week Low \$0.84
One-Year Return (%) -88.26
Beta 1.15
Average Daily Volume (sh) 107,996

Shares Outstanding (mil) 4
Market Capitalization (\$mil) \$3
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)
2022	0.6A	0.2A	0.3A	1.4A	2.5A
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	0.5E	3.7E

Earnings per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-0.06A	-0.24A	-5.13A	-2.55A	-1.48A
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	-1.26E	-4.73E

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

Update

Ensysce Biosciences (ENSC) is a clinical stage company that is developing novel opioids that provide the needed pain relief, while greatly limiting the potential for abuse and overdoses that have plagued the American public.

Company management has recently announced that it has received international patents for its technology that we believe expands its patient impact potential as well as the commercial opportunity for the company. First, the company's ADHD therapy with built-in abuse and overdose protection received a Notice of Allowance from the European Patent Office for the issuance of a patent. According to the company, this newly allowed patent, covering both composition of matter and method of use claims, adds to the Ensysce patent portfolio and secures its subject-matter authority in developing safer treatments for ADHD, a condition affecting millions of children and adults worldwide.

As a reminder, amphetamine stimulants remain the standard of care for ADHD but carry well-documented risks of abuse, dependence, and overdose. Approximately 3.9 million people aged 12 or older misused prescription stimulants in 2023 according to the Department of Health and Human Services. The company's treatment, PF8026, is another drug candidate in a new class of ADHD medications that directly address these risks. Unlike traditional formulations, Ensysce's prodrug design prevents common abuse routes such as nasal inhalation and incorporates MPAR overdose protection, which we have written about extensively and has extensive positive test results.

Second, the company received a Notice of Allowance from the Brazilian Patent Office for the issuance of a patent covering additional opioid families, utilizing the company's proprietary TAAP and MPAR technologies. The combination of these two announcements furthers out belief in the future extensive and growing revenue opportunities for the company.

This builds on other recent developments, such as an announcement late last year that it has enrolled the first patient in the pivotal Phase 3 clinical trial of PF614—the company's lead product candidate. As a reminder to investors new to the ENSC story, which is one we're very excited about, the company is developing a next-generation opioid therapy that combines effective analgesia with built-in protection against both abuse and overdose—a rare and compelling value proposition in our view. PF61 leverages a proprietary technology called *TAAP* ("Trypsin-Activated Abuse Protection"), which renders oxycodone inactive until it reaches the small intestine, significantly reducing its potential for misuse. This is not just a reformulation; it's a fundamental rethinking of how opioids can be delivered with safety in mind. The commencement of a Phase 3 trial is a major milestone on the way to potential commercialization and redefining pain care.

But Ensysce isn't stopping there: building on PF614, they have created PF614-MPAR, a combination therapy that adds *MPAR* ("Multi-Pill Abuse Resistance") technology. This innovation is designed to "switch off" further opioid release when more than the prescribed dose is taken, effectively activating an overdose protection mechanism. It's a breakthrough in concept—and importantly, the U.S. Food and Drug Administration has recognized its potential, granting Breakthrough Therapy designation.

Beyond pain management, Ensysce is expanding its impact into the treatment of opioid use disorder (OUD). Their lead OUD candidate, **PF9001**, combines the TAAP and MPAR platforms to potentially offer a safer methadone alternative—with oral delivery, reduced cardiovascular risk, and built-in overdose protection. They recently secured a U.S. patent for PF9001, adding strength to their intellectual property portfolio.

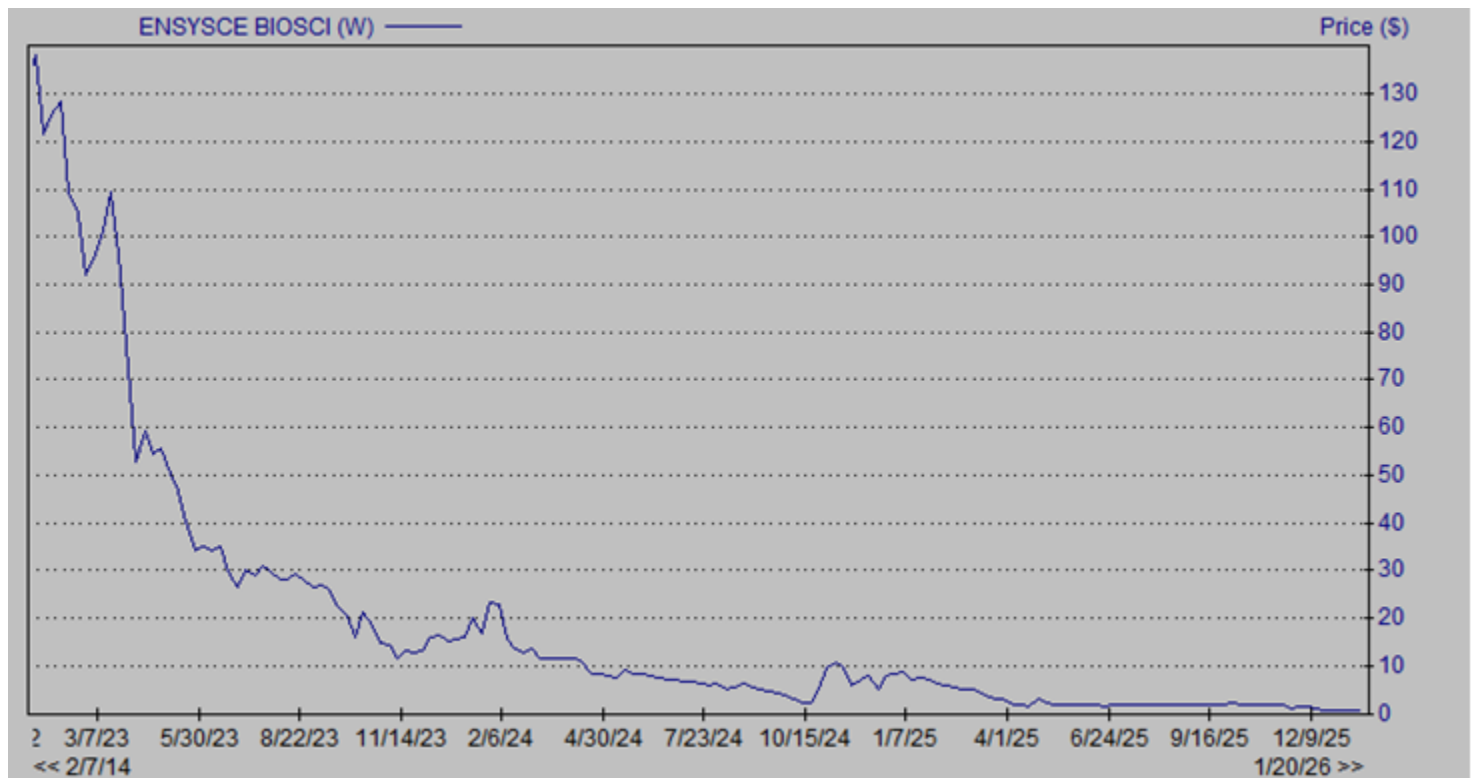
Strategically, Ensysce's management is executing with discipline. Their manufacturing partnerships for PF614 and PF614-MPAR are already in place, positioning the company for efficient scale-up once regulatory approvals move forward. Their collaborative relationship with the FDA, especially around the overdose protection labeling and streamlined regulatory path, underscores not only scientific innovation but also regulatory savvy and further underscores the positive path management is pursuing.

We have written for some time how important the work ENSC is doing is and continue to believe that. We also believe that investors who invest in such important work have the potential to be rewarded quite well as these solutions to a problem plaguing thousands of families come to fruition. We encourage investors to take a look at ENSC and consider the stock before the anticipated positive testing results from this current trial begin to come in.

PROJECTED INCOME STATEMENT & BALANCE SHEET

Ensysce Biosciences										
Income Statement and Balance Sheet										
	1Q/2024A	2Q/2024A	3Q/2024A	4Q/2024A	1Q/2025A	2Q/2025A	3Q/2025A	4Q/2025E	12/2026E	
Income										
Federal Grants	305,722	181,797	3,418,853	1,303,659	1,319,772	1,371,438	493,104	502,966	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	(778,904)	(947,229)	(1,690,674)	(3,802,630)	(1,885,528)	(1,923,430)	(2,954,909)	(3,014,007)	(1,979,804)	
Other										
Sales/Marketing	0	0	0	0	0	0	0	0	(250,000)	
Admin/general/other	(1,369,782)	(1,190,010)	(1,083,433)	(1,077,505)	(1,379,817)	(1,178,365)	(1,279,290)	(1,304,876)	(1,448,808)	
Interest	(1,248,065)	0	0	0	(3,856)	(3,160)	0	0	(15,424)	
Adjustments to net income	(25,534)	(12,351)	17,023	12,054	0	0	11,967	0	0	
Gain/loss	(3,116,563)	(1,967,793)	661,769	(3,564,422)	(1,945,573)	(1,733,517)	(3,729,128)	(3,815,917)	(928,612)	
Loss attributable to noncontrolling	(74)	0	0	0	0	(166)	0	0	0	
Deemed div. rel.to warrants	290	0	0	0	0	0	0	0	0	
Net Loss Attr. to Common S/H	(3,116,779)	(1,967,793)	661,769	(3,564,422)	(1,945,573)	(1,733,351)	(3,729,128)	(3,815,917)	(928,612)	
Shares	5,694,466	8,817,316	9,890,390	1,229,111	1,401,144	2,202,299	2,890,797	3,035,337	3,187,104	
Per share	(\$0.55)	(\$0.22)	\$0.07	(\$2.90)	(\$1.39)	(\$0.79)	(\$1.29)	(\$1.26)	(\$0.29)	
Assets										
Cash	3,404,349	1,043,231	4,153,592	3,502,077	3,052,491	2,211,575	1,673,218	2,509,827	3,205,116	
Other	1,669,841	1,752,389	5,231,132	2,095,155	1,559,383	3,362,880	1,506,246	1,536,371	1,637,352	
Total Assets	5,074,190	2,795,620	9,384,724	5,597,232	4,611,874	5,574,455	3,179,464	4,046,198	4,842,468	
Liabilities										
Accounts Payable	981,720	481,971	1,967,573	1,357,079	615,295	1,042,832	463,458	472,727	633,754	
Other liabilities	654,408	824,649	834,211	850,118	1,145,881	1,470,178	1,841,257	1,878,082	1,180,257	
Long-term liabilities	17,433	9,615	3,213	10,096	130,180	1,033	35	36	143	
Total liabilities	1,653,561	1,316,235	2,804,997	2,217,293	1,891,356	2,514,043	2,304,750	2,350,845	1,814,154	
Shareholder deficit/surplus	3,420,629	1,479,385	6,579,727	3,379,939	2,720,518	3,060,412	874,714	1,695,353	3,028,314	
Total liabilities and shareholder equity	5,074,190	2,795,620	9,384,724	5,597,232	4,611,874	5,574,455	3,179,464	4,046,198	4,842,468	

HISTORICAL STOCK PRICE



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