

# Zacks Small-Cap Research

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## Ensysce Biosciences

(ENSC-NASDAQ)

### ENSC: Phase 3 Trial Enrolls 1<sup>st</sup> Patient

### OUTLOOK

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.

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 achieved a crucial milestone-enrolling the first patient in its Phase 3 trial of PF614-its lead drug candidate that aims to redefine pain care.

Current Price (12/08/25) \$1.60  
Valuation **\$16.45**

### SUMMARY DATA

52-Week High **\$9.98**  
52-Week Low **\$1.57**  
One-Year Return (%) **-79.98**  
Beta **1.15**  
Average Daily Volume (sh) **81,564**

Shares Outstanding (mil) **3**  
Market Capitalization (\$mil) **\$6**  
Short Interest Ratio (days) **N/A**  
Institutional Ownership (%) **6**  
Insider Ownership (%) **8**

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.

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## 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.

The company announced 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
<b>Income</b>										
	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
<b>Operating Expenses</b>										
	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)
<b>Other</b>	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
<b>Gain/loss</b>		(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)
<b>Loss attributable to noncontrolling</b>		(74)	0	0	0	0	(166)	0	0	0
<b>Deemed div. rel.to warrants</b>		290	0	0	0	0	0	0	0	0
<b>Net Loss Attr. to Common S/H</b>		(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)
<b>Shares</b>		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
<b>Per share</b>		(\$0.55)	(\$0.22)	\$0.07	(\$2.90)	(\$1.39)	(\$0.79)	(\$1.29)	(\$1.26)	(\$0.29)
<b>Assets</b>										
	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
<b>Total Assets</b>		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
<b>Liabilities</b>										
	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
<b>Long-term liabilities</b>		17,433	9,615	3,213	10,096	130,180	1,033	35	36	143
<b>Total liabilities</b>		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
<b>Shareholder deficit/surplus</b>		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
<b>Total liabilities and shareholder equity</b>		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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