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Zacks Small-Cap Research

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

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Ensysce Biosciences (ENSC-NASDAQ)

ENSC: Game-changing Pain Reliever Begins Phase 3

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.

Current Price (07/15/25)	$2.11
Valuation	**$18.45**

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 announced that it has initiated its pivotal Phase 3 study of PF614. This study aims to confirm that PF614 provided powerful pain relief, while being abuse resistant at the same time.

SUMMARY DATA

52-Week High	**$10.94**
52-Week Low	**$1.66**
One-Year Return (%)	**-70.14**
Beta	**0.98**
Average Daily Volume (sh)	**68,653**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$5**
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	1.3E	1.4E	1.4E	5.4E

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	-0.75E	-0.72E	-0.70E	-3.56E

*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 was initiating its Phase 3 trial of PF614, which is the company's lead product candidate. We have outlined how effective PF614 has been shown to be at mimicking the pain relief ability of an opioid, while also having characteristics that make it resistant to abuse. This Phase 3 trial aims to confirm those previously seen results, setting it up for commercialization. The potential importance of this drug cannot be overstated in our view. The opioid addiction epidemic has cost hundreds of thousands of American lives, while the fear of such addiction has prevented patients from getting the pain relief they so desperately need. PF614 has the opportunity to change that equation.

We also want to remind investors that the company's PF614-MPAR product is progressing to Part 2 of a three-part study, which will be used to perfect the final drug product to more into commercialization.

As part of that testing, earlier in the year, the company released data on its PF614-MPAR compound, which is designed to treat pain and provided overdose protection. In the study, subjects were received up to five 100 mg doses of the overdose-protected PF614-MPAR versus the unprotected PF614. The data showed that the maximum amount of oxycodone released from PF614-MPAR, when three or more doses were taken at one time was reduced compared to that released following the consumption of same amount of PF614 alone, evidence of overdose protection. When five doses of PF614-MPAR were administered, overdose protection was appropriately greater than that observed from three dose units. Additionally, safety data from the trial showed that there were no unexpected adverse events from either PF614 or PF614-MPAR.

This data further confirms our belief that ENSC is developing a potentially game-changing treatment that could change patients' lives by providing much-needed pain relief, while greatly reducing the risk of abuse. Company management noted that they will use this data in discussions with the FDA regarding the full development plan for this compound.

Illustrating the belief in this treatment, in 2024, the company announced that it has received a $14 million grant from the National Institute of Health (NIH) for the continued clinical development of PF614-MPAR—the company's abuse-deterrent opioid with overdose protection. The award will be paid over three years and, according to the company, allow for the completion of crucial clinical trials. This award creates multiple positive impacts for the company. First, the money from the grant will help fund operations and further clinical testing, while allowing the company to limit future potential dilution to shareholders. Additionally, the award represents, in our view, another positive vote from a respected medical organization that has seen the initial data and believes in the potential benefits of this treatment.

We aren't going to rehash recent reports that have outlined the positive test results for PF614 and PF614-MPAR. But, as a reminder, these tests have shown that PF614 can provide the much-needed pain relief that is currently available through the highly abused oxycodone, while having abuse resistant properties and lasting longer. Additionally, an important reminder that PF-614-

MPAR received an FDA grant of Breakthrough Therapy designation, which allows ENSC the opportunity to accelerate clinical programs and commercialization plans. The grant, which has been applied to fewer than 300 drugs historically, illustrates the importance and urgency that these solutions are needed. We are again reiterating our belief that the treatments being developed by Ensysce will be game changers in the pain relief market and again suggest that investors take a strong look at ENSC.

PF614-MPAR has been shown in testing to have the potential to provide much needed pain relief to patients and provides protections against taking too many pills, which often leads to debilitating addiction. The technology involved causes the drug to become inactive when dosing requirements are exceeded—greatly diminishing the “incentive” patients may have to take more than the prescribed dose.

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 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/2025E	3Q/2025E	4Q/2025E	12/2026E
Income										
	Federal Grants	305,722	181,797	3,418,853	1,303,659	1,319,772	1,346,167	1,373,091	1,400,553	0
	Sales	0	0	0	0	0	0	0	0	10,000,000
Operating Expenses										
	COGS	0	0	0	0	0	0	0	0	(1,000,000)
	R&D	(778,904)	(947,229)	(1,690,674)	(3,802,630)	(1,885,528)	(1,923,239)	(1,961,703)	(2,000,937)	(1,979,804)
Other	Sales/Marketing	0	0	0	0	0	0	0	0	(1,000,000)
	Admin/general/other	(1,369,782)	(1,190,010)	(1,083,433)	(1,077,505)	(1,379,817)	(1,407,413)	(1,435,562)	(1,464,273)	(1,448,808)
	Interest	(1,248,065)	0	0	0	(3,856)	(3,933)	(4,012)	(4,092)	(15,424)
	Adjustments to net income	(25,534)	(12,351)	17,023	12,054	0	0	0	0	0
Gain/loss		(3,116,563)	(1,967,793)	661,769	(3,564,422)	(1,945,573)	(1,984,484)	(2,024,174)	(2,064,658)	6,571,388
Loss attributable to noncontrolling		(74)	0	0	0	0	0	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)	(1,984,484)	(2,024,174)	(2,064,658)	6,571,388
Shares		5,694,466	8,817,316	9,890,390	1,229,111	1,401,144	2,661,896	2,794,991	2,934,740	3,081,477
Per share		($0.55)	($0.22)	$0.07	($2.90)	($1.39)	($0.75)	($0.72)	($0.70)	$2.13
Assets										
	Cash	3,404,349	1,043,231	4,153,592	3,502,077	3,052,491	2,899,866	2,754,873	2,617,129	3,205,116
	Other	1,669,841	1,752,389	5,231,132	2,095,155	1,559,383	1,590,571	1,622,382	1,654,830	1,637,352
Total Assets		5,074,190	2,795,620	9,384,724	5,597,232	4,611,874	4,490,437	4,377,255	4,271,959	4,842,468
Liabilities										
	Accounts Payable	981,720	481,971	1,967,573	1,357,079	615,295	627,601	640,153	652,956	633,754
	Other liabilities	654,408	824,649	834,211	850,118	1,145,881	1,168,799	1,192,175	1,216,018	1,180,257
Long-term liabilities		17,433	9,615	3,213	10,096	130,180	132,784	135,439	138,148	134,085
Total liabilities		1,653,561	1,316,235	2,804,997	2,217,293	1,891,356	1,929,183	1,967,767	2,007,122	1,948,097
Shareholder deficit/surplus		3,420,629	1,479,385	6,579,727	3,379,939	2,720,518	732,713	827,224	927,618	2,894,371
Total liabilities and shareholder equ		5,074,190	2,795,620	9,384,724	5,597,232	4,611,874	2,661,896	2,794,991	2,934,740	4,842,468

HISTORICAL STOCK PRICE



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