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Zacks Small-Cap Research

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Ensysce Biosciences (ENSC-NASDAQ)

ENSC: Key Approval for Test of Potential Game-Changing Drug

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 (08/10/23)	$1.96
Valuation	**$17.85**

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 continued its recent history of positive steps toward approval of its PF 614 compound by announcing a key regulatory go ahead for an important study.

SUMMARY DATA

52-Week High	**$131.00**
52-Week Low	**$1.77**
One-Year Return (%)	**-98.38**
Beta	**0.53**
Average Daily Volume (sh)	**80,711**
Shares Outstanding (mil)	**1**
Market Capitalization ($mil)	**$2**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**53**
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)
2021	N/A	N/A	1.2A	0.4E	1.7A
2022	0.6A	0.2A	0.3A	1.4A	2.5A
2023	0.8A	0.5A	0.3E	0.3E	1.9E
2024	0.2E	0.3E	0.3E	0.3E	1.1E

Earnings per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	N/A	-0.39A	-0.71A	0.45A	-1.48A
2022	-0.06A	-0.24A	-5.13A	-2.55A	11.62A*
2023	-2.08A	-0.98A	-1.08E	-1.09E	-5.23E
2024	-1.02E	-1.05E	-1.03E	-1.05E	-4.15E

*quarters don't add to yearly total in 2022 due to reverse stock split and share issuance.

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Earnings Update

- Cash and cash equivalents were $3.8 million at the end of 2Q, up from $1.4 million at the end of 1Q.
- Net loss for Ensysce for 2Q 2023 was $0.98 per share.

Company Update

ENSC stock has struggled recently, and we understand that investors can be disheartened by the dilution the company's stock has undergone as Ensysce gets much-needed funding to move toward FDA approval. But we believe the negative sentiment is overdone and the ground-breaking potential for Ensysce discoveries are not being appropriately appreciated by investors. Patience is required as the FDA approval process can be an extended one, but we believe that patience will be rewarded.

Ensysce Biosciences has been one of the companies that we cover that we believe most of America would hope is successful and one we are becoming more convinced will achieve its goals. The opioid crisis remains a plague on the American public and is destroying families and whole communities. The National Institute on Drug Abuse reported more than 106,000 overdose deaths in 2021—and that doesn't count the millions of family members and friends impacted by those deaths. Ensysce has extremely promising technology that is abuse resistant, while still providing the much-needed pain relief that many Americans need with a longer lasting dose than is bioequivalent OxyContin.

Our confidence in the ultimate approval of this important drug continues to grow as the company announced the approval by the Investigational Review Board (IRB) for a randomized, double-blind, placebo-controlled study of its PF614 compound. We'll defer to the Chief Medical Officer of Ensysce, Dr. Bill Schmidt, to remind us of the potential of PF614 and the importance of the just-approved study: "PF614 is a chemically modified opioid product that requires initial metabolic transformation by trypsin in the small intestine for activation to be able to relieve severe pain in patients who require an opioid-level analgesic. Over the last year, we have been able to rapidly progress the clinical development of PF614 by establishing its bioequivalence to OxyContin and by showing it has limited desirability for use by recreational drug users, both of which we believe will lead to favorable labeling claims. This new study will be critical for understanding the optimal prescribing options for surgical patients."

Dr. Lynn Kirkpatrick, CEO of Ensysce, noted that the company expects results from this trial in late 2023. It has been a long road to approval for Ensysce and PF614, as it most often is when dealing with the FDA, but we are beginning to see light at the end of the tunnel. The company continues to compile data points and safety data that both confirm what we believe the potential of PF614 is and what the company will need when it submits PF614 for full Phase 3 evaluation. The runway is getting shorter, although there can still be potholes along the way, and we believe the recent issues with ENSC stock provides an opportunity for investors before further potential positive data is reported.

The market for biotechnology stocks has been bumpy lately but we strongly believe, and have shown above, the technology being advanced by Ensysce has enormously important potential for the American public—and for investors with a higher tolerance for risk and volatility in the near term, ENSC is a stock worth looking at.

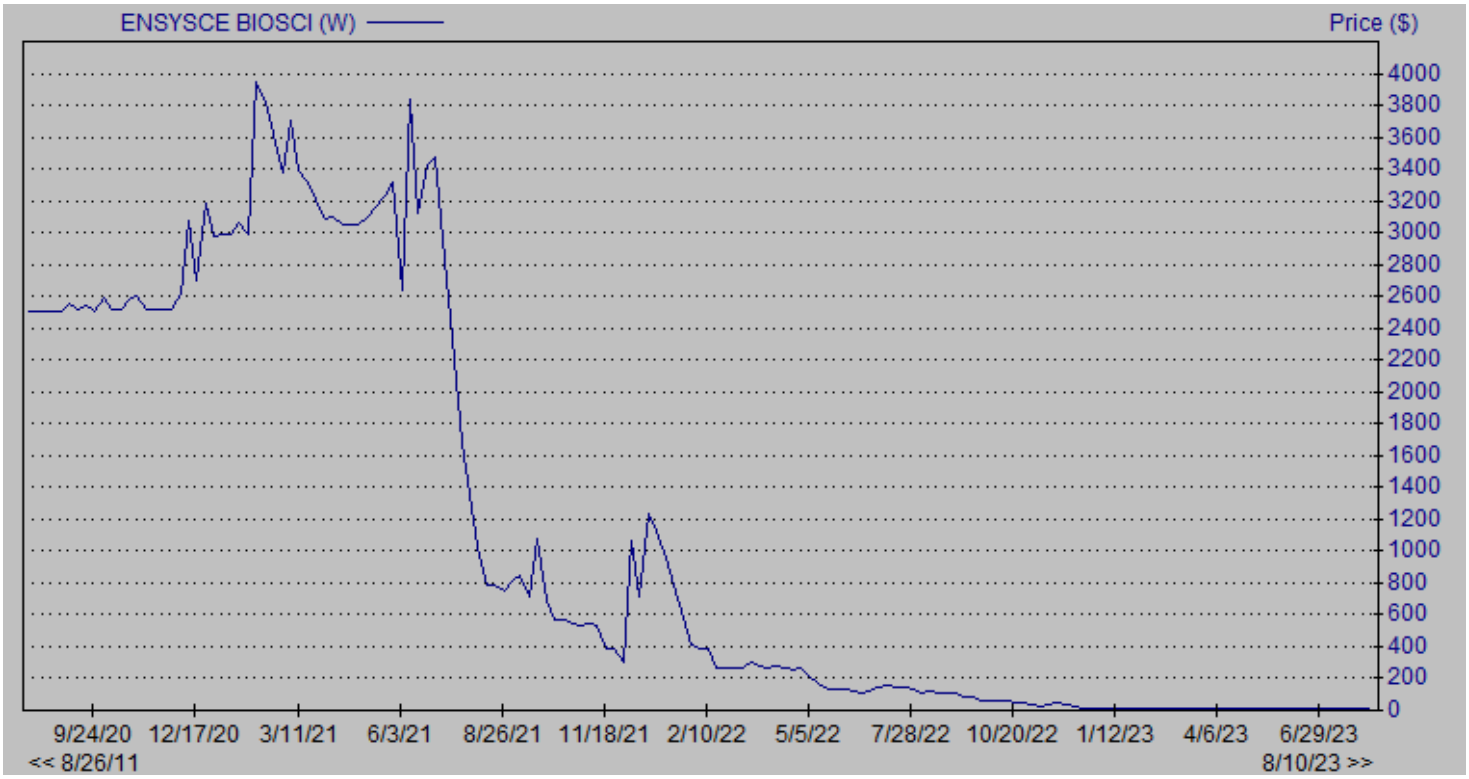
PROJECTED INCOME STATEMENT & BALANCE SHEET

Ensysce Biosciences

Income Statement and Balance Sheet

		03/2023A	06/2023A	09/2023E	12/2023E	12/2024E	12/2025E	12/2026E
Income								
	Federal Grants	789,635	490,472	279,351	279,351	1,117,404	2,200,000	0
	Sales	0	0	0	0	0	0	80,000,000
Operating Expenses								
	COGS	0	0	0	0	0	0	(12,800,000)
	R&D	(1,796,015)	(1,643,726)	(1,725,912)	(1,812,208)	(7,248,832)	(7,611,273)	(7,991,837)
Other	Sales/Marketing	0	0	0	0	0	0	(8,000,000)
	Admin/general/other	(1,554,855)	(1,086,048)	(1,140,350)	(1,197,368)	(4,789,472)	(5,028,945)	(5,280,393)
	Adjustments to net income	369,429	0	0	0	0	0	0
Gain/loss		(2,191,806)	(2,239,302)	(2,586,912)	(2,730,225)	(10,920,899)	(10,440,219)	66,727,771
Loss attributable to noncontrolling interest		3,941	7,060					
Deemed div. related to warrants down round pr		(8,309)	(3,729)					
Shares		1,054,202	2,274,113	2,387,819	2,507,210	2,632,570	2,764,199	2,902,408
Per share		($2.08)	($0.98)	($1.08)	($1.09)	($4.15)	($3.78)	$22.99
Assets								
	Cash	1,415,765	3,829,482	4,503,081	4,548,112	4,775,517	5,014,293	5,265,008
	Other	2,499,097	2,528,141	3,786,747	3,824,614	4,015,845	4,216,637	4,427,469
Total Assets		3,914,862	6,357,623	8,289,828	8,372,726	8,791,363	9,230,931	9,692,477
Liabilities								
	Accounts Payable	1,598,166	1,274,629	1,285,514	1,324,079	1,363,802	1,404,716	1,446,857
	Other liabilities	2,377,802	1,242,491	10,624,450	10,943,184	11,271,479	11,609,623	11,957,912
Long-term liabilities		91,318	47,696	2,801,796	2,885,850	2,972,425	3,061,598	3,153,446
Total liabilities		4,067,286	2,564,816	14,711,760	15,153,113	15,607,706	16,075,937	16,558,215
Shareholder deficit/surplus		(152,424)	3,792,807	(6,421,932)	(6,780,387)	(6,816,344)	(6,845,007)	(6,865,738)
Total liabilities and shareholder equity		3,914,862	6,357,623	8,289,828	8,372,726	8,791,363	9,230,931	9,692,477

HISTORICAL STOCK PRICE



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