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Zacks Small-Cap Research

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Ensysce Biosciences (ENSC-NASDAQ)

ENSC: *Positive Clinical Data Released*

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 (03/31/23)	$4.86
Valuation	**$43.80**

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 released results from testing of its PF614 drug that showed positive results, which should provide momentum for the stock.

SUMMARY DATA

52-Week High	**$345.74**
52-Week Low	**$4.86**
One-Year Return (%)	**-98.14**
Beta	**0.58**
Average Daily Volume (sh)	**130,431**
Shares Outstanding (mil)	**1**
Market Capitalization ($mil)	**$6**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**39**
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	0.6E	0.7E	0.8E	0.8E	2.9E
2024	0.5E	0.5E	0.6E	0.6E	2.2E

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	-21.00E	-24.00E	-15.00E	-16.35E	-78.04E
2024	-12.00E	-15.00E	-15.00E	-16.20E	-58.20E

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

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Company Update

Enscyse Biosciences has been one of the companies that we cover that we believe most of America is hoping is successful. 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 million of family members and friends impacted by those deaths. Enscyse has extremely promising technology that aims to eliminate the ability to overdose or abuse the pain reliever, while still providing the much-needed pain relief that many Americans need.

The company recently provided a couple of updates—the most important of which was the announcement of positive results from the Oral Human Abuse Potential Trial for PF614. These results were as we expected, but don't believe investors had given them credit for. The company announced that the study "met all key endpoints" and the drug had significantly lower "Drug Liking" scores than the oxycodone product. The company noted that these results should allow Enscyse to enter into the end of phase 2 discussions with the FDA for the commencement of phase 3 trials.

Dr. Lymm Webster, Senior Fellow, Center for US Policy and considered a leading expert on HAP studies noted, "These results are very positive…and PF614 may have an important place in therapy." These comments further our belief that ENSC is a stock that is undervalued by investors who are failing to recognize the potential of this drug.

The company also recently announced that it had completed enrollment in the final stage of the Phase I study of PF614-MPAR. This product is a combination product designed to limit the ability of people to overdose on the opioid. The company's lead product, PF614, features the company's TAAP (Trypsin-Activated Abuse Protection), which requires the digestive enzyme trypsin to be activated. This prevents the ability of a user to achieve a greater reaction by injecting, chewing or snorting the drug. The company is focused on opioid abuse but this technology could be used in virtually all prescription drugs. It should also be noted that testing has shown that PF614 provides over 12 hours of pain relief, which the company notes is 30% longer than abuse-deterrent opioid products already on the market. Additionally, these current abuse-deterrent products are still able to be crushed, chewed or injected—spiking blood levels of the opioid and resulting in a euphoric rush.

The full deterrent for abuse occurs when the PF614 technology is coupled with the company's MPAR technology. The MPAR technology allows trypsin to digest and activate the opioid up the prescribed level. Beyond that level, either through an intentional or accidental overdose, MPAR inhibits trypsin, preventing the activation of the opioid beyond the prescribed level.

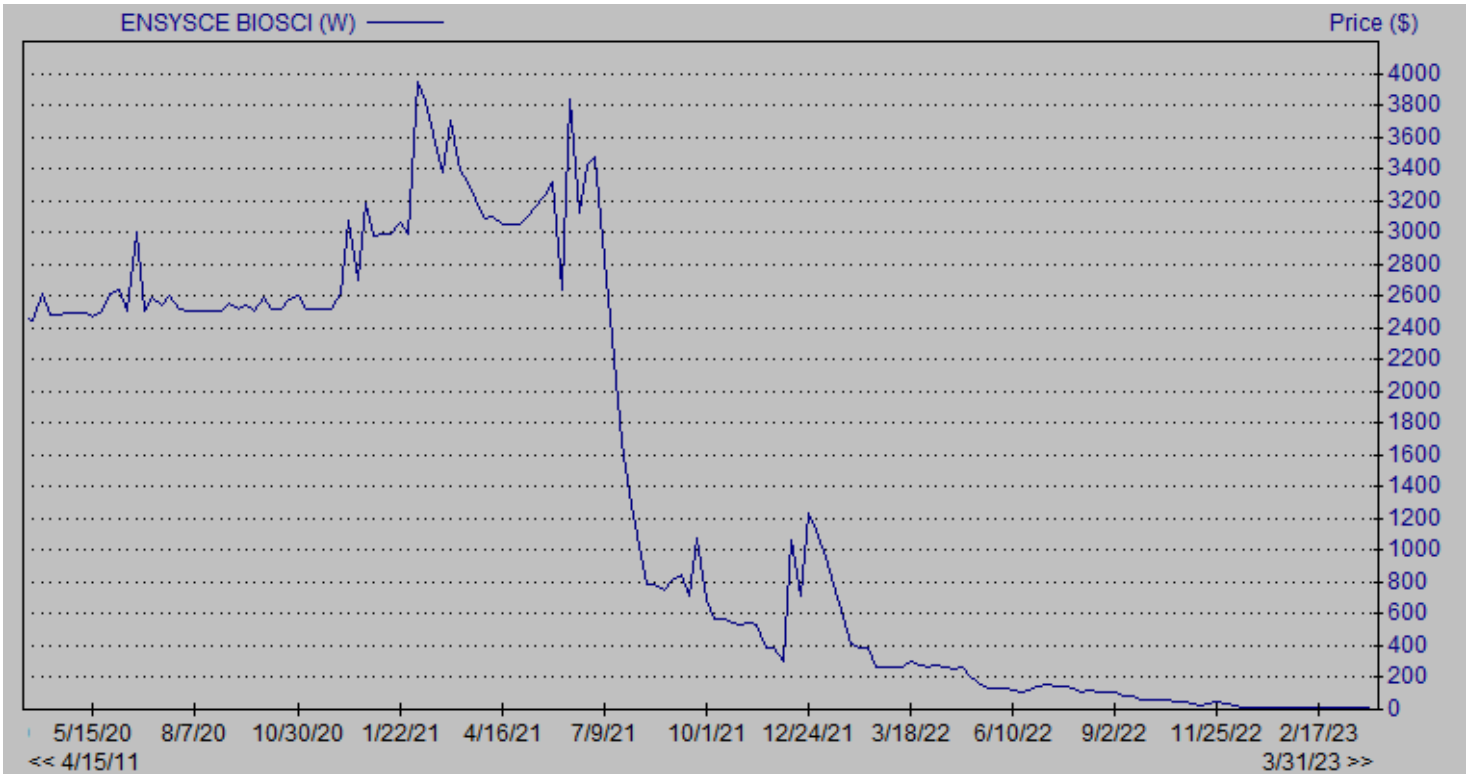
A comment from the primary doctor, Dr. Maria Bermudez, in charge of the trials employed by the company tasked with performing the Phase I study, Quotient Sciences, probably tells the story better than anything else. The doctor recently noted, "This is the most interesting Phase 1 study I have been involved with. I have been impressed by the positive data that has been generated, it is encouraging to be able to contribute to a solution to one of this century's biggest health crises. I look forward to the final results from the study."

The company also announced full-year 2022 financial results as well as initiated a reverse 1:12 stock split. The most important number from the release was the cash on hand, which was $3.1 million as of December 31, 2022, but was bolstered by an additional $3.0 million from a registered direct offering. Research and development costs were higher in 2022, much as we expected due to the clinical costs associated with programs for PF614 and PF614-MPAR. Management continues to manage the balance sheet of the company in a way that allows this crucial treatment to continue

toward commercialization and the release of the 2022 results bolsters our confidence in the path the management has the company on.

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.

HISTORICAL STOCK PRICE



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