January 23, 2024

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: Drug Earns Crucial BTD Designation

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 (01/22/24)	$1.14
Valuation	**$17.50**

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 received the coveted Breakthrough Therapy Designation (BTD) for its PF614-MPAR treatment. This action illustrates the importance of the potential for this treatment as viewed by the FDA.

SUMMARY DATA

52-Week High	**$9.64**
52-Week Low	**$0.80**
One-Year Return (%)	**-86.61**
Beta	**0.88**
Average Daily Volume (sh)	**120,893**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$4**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**31**
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	0.4A	0.3E	2.0E
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	-0.87A	-0.93E	-4.86E
2024	-0.85E	-0.86E	-0.89E	-0.93E	-3.53E

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

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Update

Ensysce Biosciences (ENSC) announced that its next generation opioid, PF614-MPAR, has been granted Breakthrough Therapy Designation (BTD) by the FDA. This designation is extremely valuable and has been granted to fewer than 300 drugs, according to the FDA and punctuates our continued belief that PF614-MPAR has the chance to be a game-changing therapy.

The Breakthrough Therapy Designation is a program established by the U.S. Food and Drug Administration (FDA) to expedite the development and review of drugs that show significant promise in treating serious or life-threatening conditions. This designation is intended for therapies that demonstrate substantial improvement over existing treatments or address unmet medical needs.

Key features of Breakthrough Therapy Designation include:

1. **Expedited Development and Review:** The designation aims to accelerate the development and review process, allowing for more frequent communication between the FDA and the drug developer. This collaboration is intended to facilitate efficient drug development.
2. **Intensive Guidance:** Sponsors of drugs granted Breakthrough Therapy Designation receive enhanced guidance from the FDA throughout the development process. This involves discussions on the drug's development plan, design of clinical trials, and other key aspects.
3. **Priority Review:** Drugs that receive Breakthrough Therapy Designation are eligible for priority review, which shortens the standard review time. This is particularly beneficial for bringing important therapies to patients more quickly.
4. **Rolling Review:** Instead of waiting until a New Drug Application (NDA) is complete, the FDA allows for a rolling review of the data. This means that the agency can review portions of the application as they become available, expediting the overall review process.

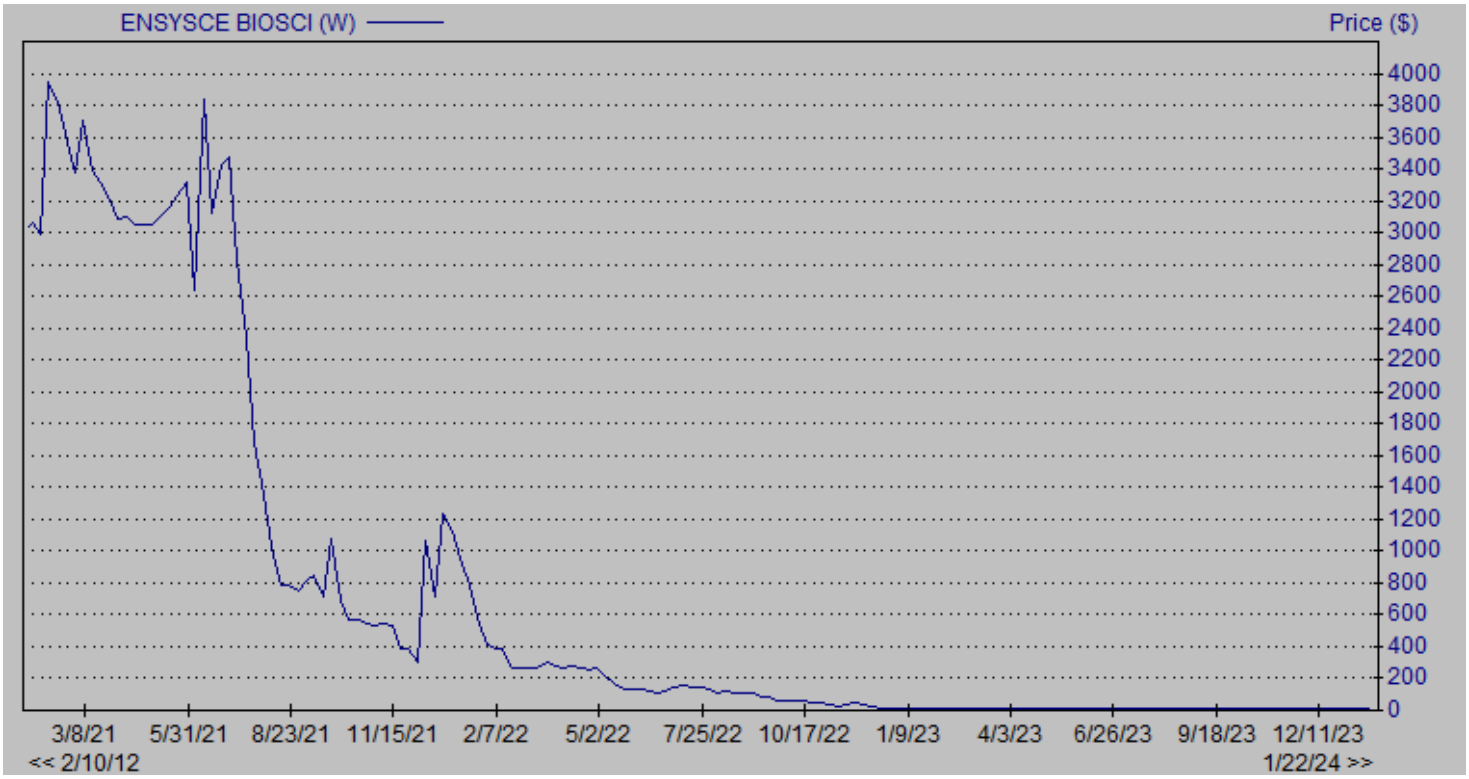
The Breakthrough Therapy Designation is intended to encourage the development of innovative and promising therapies, especially those addressing serious medical conditions for which there are limited or no treatment options-making the Ensysce therapy a perfect candidate.

Ensysce Biosciences continues to be 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 entire communities. The National Institute on Drug Abuse reported more than 107,000 overdose deaths in 2022—and that doesn't count the millions of family members and friends impacted by those deaths. Ensysce has extremely promising technology in the form of PF614-MPAR that is abuse resistant, while still providing the much-needed pain relief that many Americans need with a longer lasting dose than its bioequivalent OxyContin.

PF614-MPAR has been shown in testing to have the potential to provide much needed pain relief to patients but 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.

Our confidence in the ultimate approval of this important drug continues to grow as the company adds the BTD designation to the Fast Track designation already received for PF614 and continues to obtain the financing needed to continue the testing process. Events such as the BTD designation can happen quickly and without notice, illustrating why we have been suggesting investors look into ENSC before these events occur. Major tests are coming in the not-to-distant future, and we believe, based on the data we've seen from earlier tests, that the results will be quite positive and propel the stock higher.

HISTORICAL STOCK PRICE



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