March 11, 2025

# 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: NDA Submission in Sight

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 (3/10/25) | $4.90 |
| 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 4Q2024 results that reflected good cash on hand as well as highlighting the progress for its signature non-opioid pain reliever and its plan for submitting an NDA.

### SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$12.64** |
| **52-Week Low** | **$2.52** |
| **One-Year Return (%)** | **-57.36** |
| **Beta** | **0.64** |
| **Average Daily Volume (sh)** | **13,103** |
| **Shares Outstanding (mil)** | **1** |
| **Market Capitalization ($mil)** | **$7** |
| **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 | 0.0E | 0.0E | 0.0E | 0.0E | 0.0E |

**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 | -4.50E | -4.50E | -3.00E | -1.81E | -14.81E |

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

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## Update

Ensysce Biosciences (ENSC) released its 4Q2024 results that showed a good cash balance of $3.5 million due in large part to the financing activities management has undertaken which we've described in earlier reports, as well as a focus on controlling administrative expenses.

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.

Management also noted that it has received positive feedback on its Phase 3 study design for PF614 and is planning on starting enrollment in this crucial study in 2Q2025. Management also noted that the company remains on track for a New Drug Application submission in 2026. Additionally, earlier this year, the company announced a critical partnership for the manufacturing and commercialization of both of the company's products.

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.

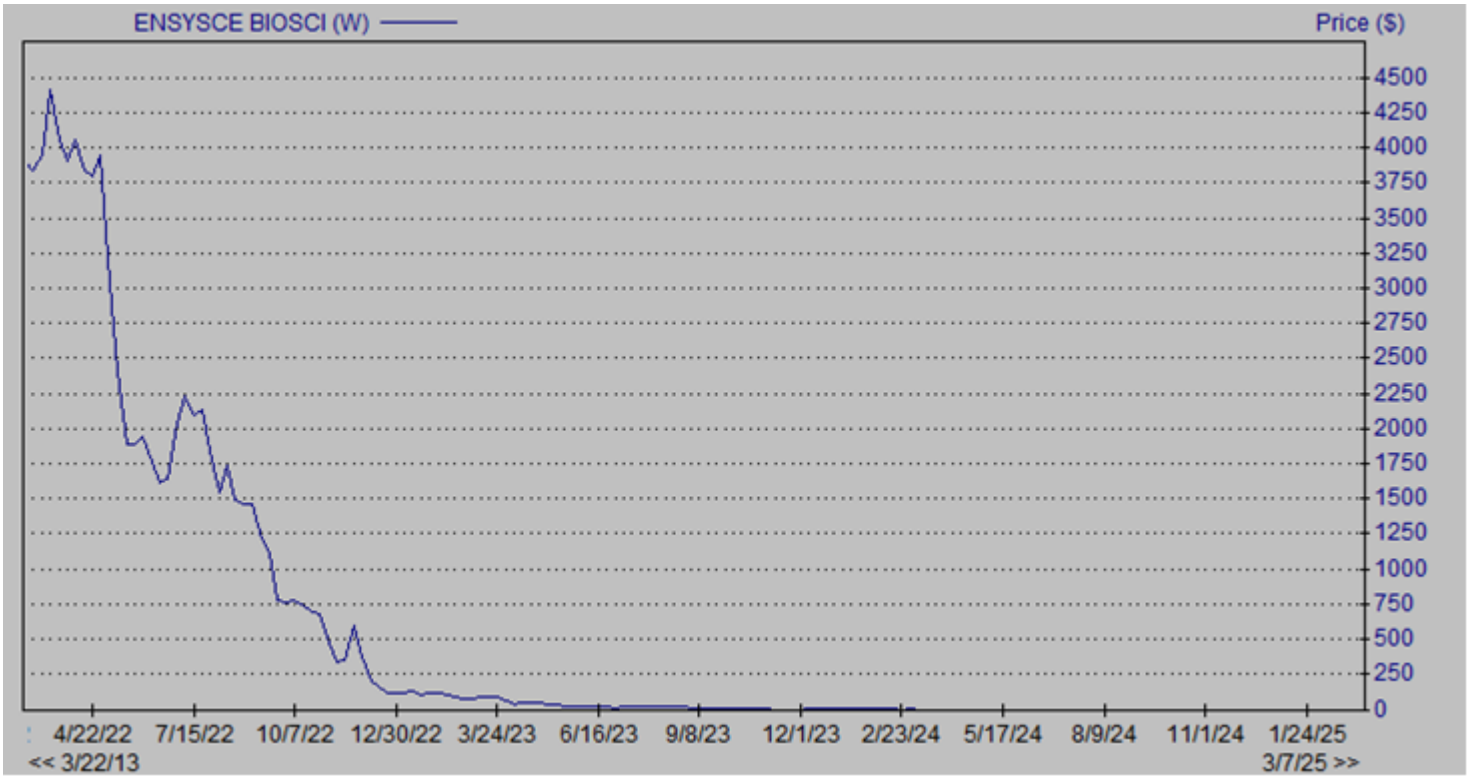
Ensysce Biosciences continues to be one of the companies that we cover that we believe most of America would hope is successful and one we are becoming more convinced will achieve its goals. The opioid crisis remains a plague on the American public and is destroying families and entire communities. The 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 and PF614-MPAR that are abuse resistant, while still providing the much-needed pain relief that many Americans need with a longer lasting dose than its bioequivalent OxyContin.

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 | | | | | | | | |
| | | 4Q/2023A | 1Q/2024A | 2Q/2024A | 3Q/2024A | 4Q/2024A | 12/2025E | 12/2026E |
| **Income** | | | | | | | | |
| | Federal Grants | 515,032 | 305,722 | 181,797 | 3,418,853 | 1,303,659 | 0 | 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 | (2,232,760) | (778,904) | (947,229) | (1,690,674) | (3,802,630) | (15,210,520) | (15,971,046) |
| **Other** | Sales/Marketing | 0 | 0 | 0 | 0 | 0 | 0 | (8,000,000) |
| | Admin/general/other | (1,786,633) | (1,369,782) | (1,190,010) | (1,083,433) | (1,077,505) | (4,310,020) | (4,525,521) |
| | Interest | 0 | (1,248,065) | 0 | 0 | 0 | 0 | 0 |
| | Adjustments to net income | 0 | (25,534) | (12,351) | 17,023 | 12,054 | 48,216 | 192,864 |
| | | | | | | | | |
| **Gain/loss** | | (3,504,361) | (3,116,563) | (1,967,793) | 661,769 | (3,564,422) | (19,472,324) | 59,696,297 |
| **Loss attributable to noncontrolling interest** | | 66 | (74) | 0 | 0 | 0 | 0 | 0 |
| **Deemed div. related to warrants down round provision** | | | 290 | 0 | 0 | 0 | 0 | 0 |
| **Net Loss Attributable to Common Shareholders** | | (3,504,427) | (3,116,779) | (1,967,793) | 661,769 | (3,564,422) | (19,472,324) | 59,696,297 |
| **Shares** | | 3,101,146 | 5,694,466 | 8,817,316 | 9,890,390 | 1,229,111 | 1,315,149 | 1,407,209 |
| | | | | | | | | |
| **Per share** | | ($1.13) | ($0.55) | ($0.22) | $0.07 | ($2.90) | ($14.81) | $42.42 |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| **Assets** | | | | | | | | |
| | Cash | 1,123,604 | 3,404,349 | 1,043,231 | 4,153,592 | 3,502,077 | 3,677,181 | 3,861,040 |
| | Other | 1,584,481 | 1,669,841 | 1,752,389 | 5,231,132 | 2,095,155 | 2,199,913 | 2,309,908 |
| **Total Assets** | | 2,708,085 | 5,074,190 | 2,795,620 | 9,384,724 | 5,597,232 | 5,877,094 | 6,170,948 |
| **Liabilities** | | | | | | | | |
| | Accounts Payable | 1,936,007 | 981,720 | 481,971 | 1,967,573 | 1,357,079 | 1,397,791 | 1,439,725 |
| | Other liabilities | 1,396,957 | 654,408 | 824,649 | 834,211 | 850,118 | 875,622 | 901,890 |
| **Long-term liabilities** | | 26,388 | 17,433 | 9,615 | 3,213 | 10,096 | 10,399 | 10,711 |
| **Total liabilities** | | 3,359,352 | 1,653,561 | 1,316,235 | 2,804,997 | 2,217,293 | 2,283,812 | 2,352,326 |
| **Shareholder deficit/surplus** | | (651,267) | 3,420,629 | 1,479,385 | 6,579,727 | 3,379,939 | 3,593,282 | 3,818,622 |
| **Total liabilities and shareholder equity** | | 2,708,085 | 5,074,190 | 2,795,620 | 9,384,724 | 5,597,232 | 5,877,094 | 6,170,948 |

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