Ensysce Biosciences, Inc. (NASDAQ: ENSC)

Ensysce™ biosciences

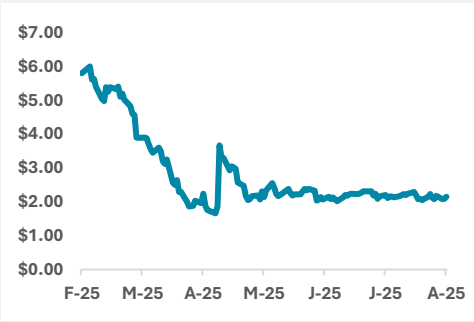
Key Statistics	
52 Week Range	$1.62-$14.67
Avg. Volume (3 months)	398.30K
Shares Outstanding	2.97M
Market Capitalization	$6.11M
EV/Revenue	NA
Cash Balance*	$2.20M
Analyst Coverage	2

*** Cash balance as of June 2025**

Revenue (in $ mm)			
Dec - FY	2024A	2025E	2026E
1Q	0.31	1.32	0.00
2Q	0.18	1.37	0.00
3Q	3.42	0.00	0.00
4Q	1.30	0.00	0.00
FY	5.21	2.69	0.00

EPS (in $)			
Dec - FY	2024A	2025E	2026E
1Q	(8.21)	(1.39)	(0.82)
2Q	(3.35)	(0.79)	(0.46)
3Q	1.00	(0.83)	(0.36)
4Q	(2.90)	(0.82)	(0.59)
FY	(11.45)	(3.83)	(2.23)

Stock Price Chart (in $)



Hunter Diamond, CFA
research@diamondequityresearch.com

Ensysce Biosciences, Inc. – Q2 2025 Marks Pivotal Transition to Late-Stage Development with PF614 Phase 3 Launch, Positive PF614-MPAR® Interim Data, and Strategic IP Wins Supported by $5.3M NIDA Funding

Share Price	$2.06	Valuation	$22.00

Investment Highlights

- **Ensysce Achieves Major Pipeline Milestones in Q2 2025 with PF614 Phase 3 Launch, PF614-MPAR® Overdose Protection Program Advances, and New OUD Patent:** In the quarter ended June 30, 2025, Ensysce Biosciences advanced multiple clinical and strategic initiatives that solidify its position in next-generation opioid therapeutics. The period was defined by the launch of the pivotal Phase 3 PF614 trial, full enrollment in Part 2 of the PF614-MPAR-102 study, continued momentum in the OUD pipeline, and a $5.3 million NIDA installment that reinforces financial backing for the company's overdose protection platform.
  - **PF614 Phase 3 Trial Initiation:** Ensysce commenced its pivotal PF614-301 Phase 3 study in July, evaluating the use of PF614 in managing severe post-surgical pain following abdominoplasty. The trial aims to confirm PF614's ability to provide effective pain relief while reducing abuse risk through its Trypsin-Activated Abuse Protection (TAAP™) technology, which renders oxycodone inactive until enzymatically activated in the small intestine. Conducted in collaboration with Rho, Inc. (a clinical research organization with deep expertise in central nervous system (CNS) disorders and pain studies), the study represents a key milestone toward NDA submission and the introduction of a potentially safer opioid class into the pain management market.
  - **PF614-MPAR® Overdose Protection Program:** During the quarter, the company achieved full enrollment in Part 2 of the PF614-MPAR-102 study, assessing food effects on its MPAR® overdose prevention technology. With FDA Breakthrough Therapy designation and sustained NIDA funding, PF614-MPAR continues to progress toward targeted commercialization as a dual-action therapy offering both pain relief and built-in overdose resistance. The program is expected to move into Part 3 by year-end, with data informing final formulation and regulatory strategy.
  - **Opioid Use Disorder (OUD) Program Advancement:** The company continued developing PF9001, its TAAP™/MPAR®-enabled methadone analogue for OUD, designed to reduce cardiotoxicity and provide overdose protection. During the quarter, Ensysce received a Notice of Allowance from the USPTO covering the composition and use of PF9001, strengthening its patent estate and future competitive position. Supported by a multi-year HEAL grant from NIDA, PF9001 is advancing toward IND-enabling studies.

The initiation of the PF614 Phase 3 trial is an inflection point, validating Ensysce's execution capabilities and accelerating its path to market entry. With strong IP protection, compelling clinical momentum, and secure non-dilutive funding from NIDA, the company's diversified pain and OUD pipeline is well-positioned to target long term shareholder value creation.

Company Description

Ensysce Biosciences, Inc., a clinical-stage pharmaceutical company, engages in developing various prescription drugs for severe pain relief. The company's pipeline of drug candidates is developed on the back of its innovative technology platforms Trypsin Activated Abuse Protection (TAAP™), an abuse-resistant opioid prodrug technology; and Multi-Pill Abuse Resistance (MPAR™).

- **Continued Clinical Investment Balanced by Federal Grant Support in Q2 2025:** In the second quarter of 2025, Ensysce Biosciences reported a net loss attributable to common stockholders of $1.7 million, narrowing from a net loss of $2.0 million in the same period last year. Cash and cash equivalents stood at $2.2 million as of June 30, 2025, compared to $3.5 million at year-end 2024, bolstered by receipt of the $5.3 million second installment of a three-year, $15 million grant from the National Institute on Drug Abuse (NIDA). Funding recognized from federal grants totaled $1.4 million, a sharp increase from $0.2 million a year ago, driven by heightened clinical activity in the PF614-MPAR-102 study initiated in September 2024. Research and development (R&D) expenses rose to $1.9 million from $0.9 million in Q2 2024, primarily reflecting increased preclinical and clinical expenditures for PF614-MPAR. General and administrative (G&A) expenses were flat year-over-year at $1.2 million. Other income totaled $17 thousand, reversing a $12 thousand expense in the prior-year quarter. Management reiterated that, as a clinical-stage biotechnology company advancing PF614 and PF614-MPAR toward regulatory approval, it expects operating losses to continue in the near term, with non-dilutive NIDA funding providing a meaningful offset to R&D spend.

- **Valuation:** Ensysce Biosciences maintained steady progress in Q2 2025, launching its pivotal PF614 Phase 3 trial, completing enrollment for PF614-MPAR-102 Part 2, and reporting positive interim results that support the program's potential to address opioid overdose risk. The company also strengthened its intellectual property position with a Notice of Allowance for PF9001, its next-generation OUD candidate, and secured a $5.3M installment from its ongoing $15M NIDA grant, providing non-dilutive funding into 2026. While R&D expenses increased to $1.9M on increased PF614-MPAR research costs, higher federal grant revenue ($1.4M) contributed to a narrower net loss of $1.7M, down from $2.0M a year earlier. Incorporating these results, the updated share count, and a refreshed comparable company analysis, we reiterate our $22.00 per share valuation, contingent on successful execution of the company's clinical and strategic plans.

- **Positive FDA Feedback Strengthens PF614-MPAR Path to Overdose Protection Labeling:** In late July 2025, Ensysce Biosciences announced it had received constructive feedback from the U.S. FDA regarding the development of PF614-MPAR, its novel dual-action opioid analgesic with built-in abuse deterrence and overdose protection. The July 23 meeting resulted in alignment with the agency on a collaborative approach to ensure PF614-MPAR's full safety profile is reflected in potential labeling, including preparation of a dedicated Overdose Protection whitepaper. Importantly, the FDA confirmed PF614-MPAR may be eligible for the 505(b)(2) regulatory pathway, which could streamline the approval process and reduce time to market. Interim results from the PF614-MPAR study demonstrated positive safety outcomes, further reinforcing the program's potential to address the U.S. opioid crisis, which claims roughly 80,000 lives annually. Continued NIDA grant funding through 2027 provides non-dilutive capital to support ongoing clinical and non-clinical development.

Company Overview

Based in La Jolla, California, Ensysce Biosciences, Inc. (NASDAQ: ENSC) is a clinical-stage pharmaceutical company developing innovative solutions for severe pain while minimizing the risk of both drug abuse and overdose. The company is dedicated to improving prescription drug safety and performance by applying sophisticated chemistry, combined with anti-abuse and anti-overdose technologies, to change the way drugs are activated during delivery to prevent the possibility of both abuse and overdose. Ensysce's products are primarily based on its two core technology platforms - Trypsin Activated Abuse Protection (TAAP™), an abuse-resistant opioid prodrug technology, and Multi-Pill Abuse Resistance (MPAR™) platform, an overdose protection opioid prodrug technology - which can be applied to prescription drugs with a wide variety of pharmaceutical applications, driving internal growth and external partnering opportunities.

Ensysce Biosciences is a clinical-stage pharmaceutical company developing innovative solutions for severe pain while minimizing the risk of both drug abuse and overdose through its proprietary TAAP™ and MPAR™ technology platforms

Ensysce currently holds over 100 patents in 25 countries across North America, Europe, and Asia, ensuring the opportunity to address abuse globally. Leveraging its proprietary TAAP™ and MPAR™ platforms, which are well-protected by a suite of patents generated from over $100 million of research support, the company is expanding its pipeline with a primary focus on opioid pain products, including PF614, a TAAP abuse-deterrent oxycodone prodrug candidate that is in Phase II clinical trial for the treatment of acute or chronic pain and has been granted Fast Track designation by the FDA with 505(b)(2) regulatory development path; and PF614-MPAR, a combination product of PF614 and trypsin inhibitor nafamostat that is in Phase I clinical trial for overdose protection against excessive ingestion. In addition to these two lead product candidates, the company has other drugs in development for respiratory diseases and ADHD: an oral and inhalation drug product of nafamostat for use against coronaviral infections and other pulmonary diseases, such as cystic fibrosis; as well as PF8001 and PF8026, extended and immediate-release prodrugs of amphetamine for ADHD medication abuse.

Exhibit 1: Ensysce Product Pipeline. Source: Ensysce Investor Presentation

TAAP™ & MPAR™: Smart, Unique and Extensible Platforms Improving Drug Performance and Safety

Focusing on chemistry and innovation, the company has developed two novel molecular drug delivery platforms that aim to reduce the abuse of prescription drugs and inhibit overdose occurrences. The technology carries with it a wide variety of pharmaceutical applications, thus offering disruptive solutions to multiple drug abuse issues that often lead to health and humanitarian crises.

Ensysce's TAAP™ is designed to be highly resistant to tampering and abuse as compared to traditional Abuse-Deterrent Formulations (ADFs) of oxycodone

The Trypsin Activated Abuse Protection (TAAP™) is an abuse-resistant prodrug technology seeking to improve patient care while impeding prescription opioid drug abuse at the molecular level. The technology ensures that the drug consumed is released only when exposed to certain physiological conditions when taken orally (that is, when the drug is ingested and exposed to the digestive enzyme trypsin). The TAAP™ pro-drug delivery system follows a two-step mechanism of action (MoA) to deliver the API in a manner that restricts both oral and non-oral modes of abuse. The first step involves the separation and release of the amino acid chain from the drug formulation when exposed to trypsin, a proteolytic enzyme found in the lumen of the small intestine. The release is followed by a cyclization-release reaction separating the linker from the active drug to achieve ideal pharmacokinetic release and absorption of API.

The enzyme-mediated metabolic activation occurs only when the drug formulation is swallowed. The activating enzyme, in this case, Trypsin, are not present in the blood, saliva, or nasal passages; thus, there is no opportunity for activation if injected, chewed, or snorted. Further, a chemically designed release timing mechanism restricts the release of active drugs to achieve rapid, spiking blood levels and a euphoric rush.

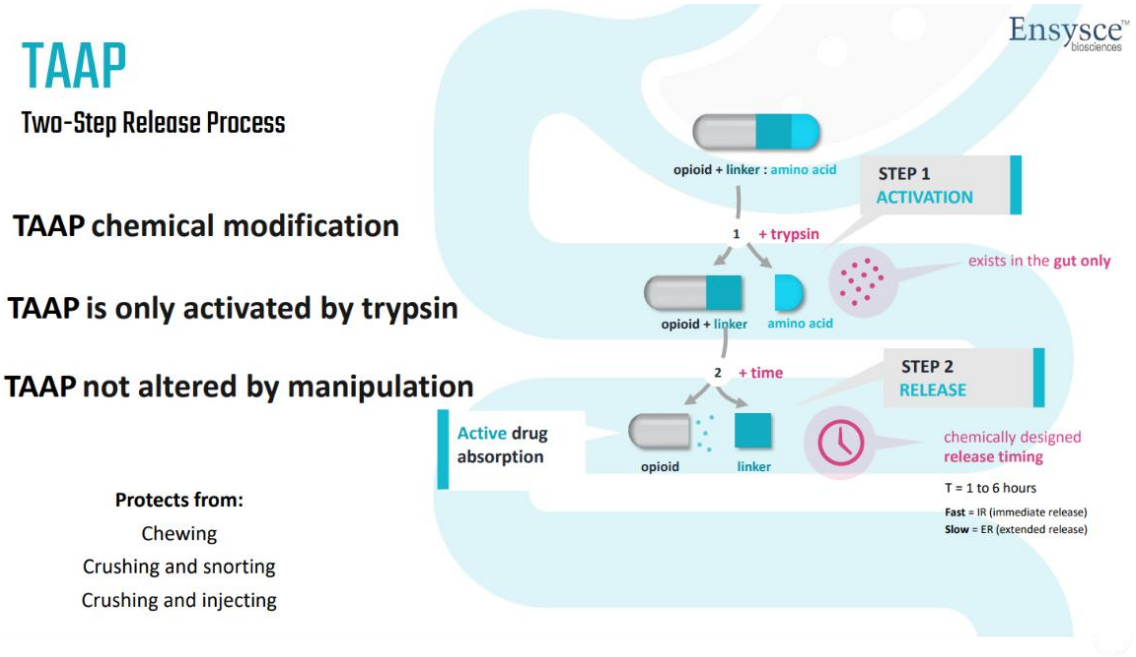


Exhibit 2: TAAP™ Mechanism of Action (MoA). Source: Company Filings

The Multi-Pill Abuse Resistant (MPAR™) platform, when combined with TAAP™ products, not only inhibits drug abuse but also protects against drug overdose. The technology leverages trypsin inhibitor, nafamostat, which is co-formulated with a TAAP™-enabled drug to provide protection against drug overdose. Nafamostat is a small molecule, highly potent protease inhibitor (trypsin inhibitor) with a steep dose-response curve. The combination drug formulation, when administered at prescribed dosage levels, would not be affected by the drug's mechanism of action or release and absorption of API. If the TAAP™ prodrug nafamostat combination (MPAR™) is administered in larger quantities than prescribed levels, the trypsin inhibitor, Nafamostat, blocks the activation process (refer to exhibit 3) and prevents the release and absorption of the API itself, thus protecting against the drug overdose.

MPAR™ provides another layer of protection and safety to Ensysce's TAAP prodrugs and holds the promise of eliminating accidental or deliberate overdose

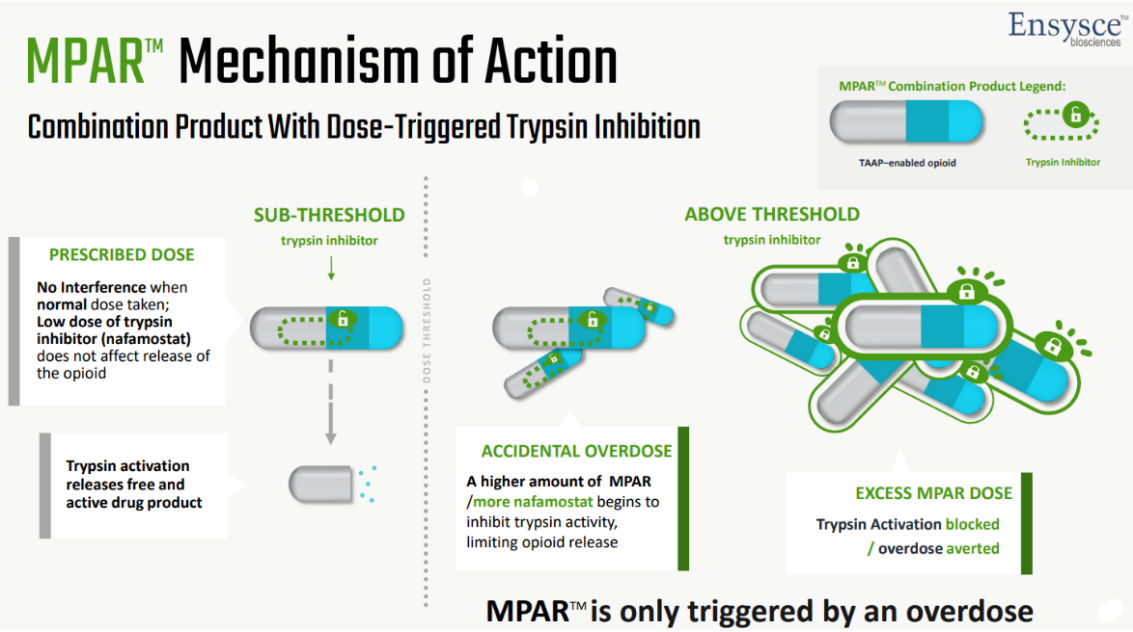


Exhibit 3: MPAR™ Mechanism of Action (MoA). Source: Company Filings

TAAP™ and MPAR™ technology platforms, when applied to numerous drug cases, hold the potential to enhance bioavailability, controlled duration of action, improved safety, and eliminate accidental or deliberate overdose. The company's diversified product pipeline targeting severe pain and CNS disorders is backed by these two technology platforms.

PF614: 'TAAP™' Oxycodone

The company's lead drug candidate, PF614, is a novel abuse-resistant TAAP™ prodrug of oxycodone currently being studied as an acute or chronic pain analgesic in phase 2 clinical trials. This innovative therapy remains the need of the hour, considering the extent of opioid abuse and opioid use disorder, particularly in North American countries. PF614 is developed on the back of the company's proprietary TAAP™ technology and uses an advantageous prodrug approach instead of the conventional active form. The drug is an extended-release prodrug of oxycodone utilizing a unique bioactivation mechanism. PF614 is pharmacologically and chemically inert until activation by pancreatic trypsin, which is followed by a second non-enzymatic cyclization producing

free oxycodone with extended-release characteristics. It has been found to resist ex vivo extraction with household chemicals and is pharmacologically inactive when administered by non-oral routes (nasal and parenteral), thereby substantially reducing its intravenous and intranasal abuse potential.

PF614-MPAR™: TAAP™ Oxycodone with Overdose Protection

PF614-MPAR™ is a novel opioid combination product in phase 1 clinical trials for a potentially safer treatment for acute or chronic pain. The drug is a combination product of PF614 and nafamostat (a trypsin inhibitor). This combination adds another layer of protection of overdose inhibition in addition to TAAP™'s abuse deterrence. The MPAR™ platform is designed in a way that prevents overdose by inhibiting the TAAP™ activation, the first in the release mechanism of PF614. The combination product is expected to prevent all major methods of drug abuse, including oral abuse, chewing, intravenous, and intranasal.

Initial pharmacokinetic data for PF614-MPAR™ demonstrates that MPAR™ can provide overdose protection by blocking the activation of PF614 and oxycodone release if overdosed

The company was awarded a grant to develop its MPAR™ platform by NIH through NIDA in September 2018. The total funding from this grant amounted to $10.8 million and has been awarded in different phases supporting the clinical development of PF614-MPAR™.

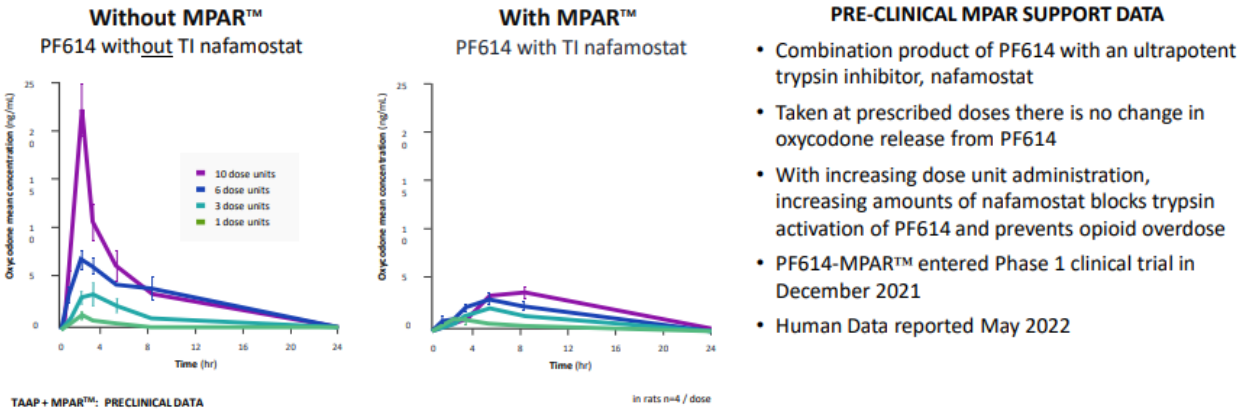


Exhibit 4: PF614-MPAR™ Pre-Clinical Data. Source: ENSC Investor Presentation

The preclinical data indicated the novel combination product limited oxycodone exposure and prevented overdose. Without MPAR™, oxycodone exposure increases substantially as the dosage level is increased, while the variability and exposure in oxycodone absorption at multiple dosage levels is significantly reduced, with MPAR™ indicating abuse inhibition properties. The Cmax at higher dosage levels in treatment without MPAR™ was significantly larger when compared to PF614 treatment with MPAR™.

Opioid Analgesics Market and Abuse-Deterrent Opioid Analgesics

Opioids are natural, synthetic, or semi-synthetic chemical substances that act on opioid receptors in the cells to provide pain-relieving effects. Major prescription opioids include Codeine, Fentanyl, Hydrocodone, Oxycodone, and Morphine, to name a few. Opioids function by mimicking natural endorphins that dampen the perception of pain and also cause euphoria. Repeated use of the drug affects brain processes and

chemistry that often leads to drug liking, tolerance, dependence, and addiction. An estimated 50.2 million U.S. adults are affected by chronic pain, while 24.4 million suffer high-impact chronic pain with work limitations.[1] Furthermore, the total estimated value of lost productivity at approximately $300 billion.[2]

The chronic pain market is currently served by pharmaceutical agents that can be potentially abused. There is an urgent need for much safer alternatives with similar efficacy profile for the underlying growing market

Opioid medications remain one of the common treatment modalities for chronic or acute pain sufferers, with 20% of patients with pain-related diagnoses receiving an opioid prescription. The U.S opioid market is currently valued at $16.28 billion and is expected to grow at 5.5% for the next eight years, reaching a value of $24.94 billion.[3] A total of 142.81 million prescriptions of opioids were dispensed in the United States in 2020.[4] The past two decades saw a considerable rise in opioid prescriptions for pain management in the United States. Given the addictive nature of the drug, there has been a significant increase in drug abuse cases and drug overdose mortality driven by illicit and prescription opioids. The prevalence of opioid misuse within chronic pain populations is estimated to be as high as 29%.[5] Additionally, 187 people die every day from opioid overdose (Rx and illicit).[4] Even though the total opioid prescriptions have declined substantially in the past 5-7 years, opioid overdose mortality remained high, aided by the increasing manufacturing of illicit opioids such as fentanyl.

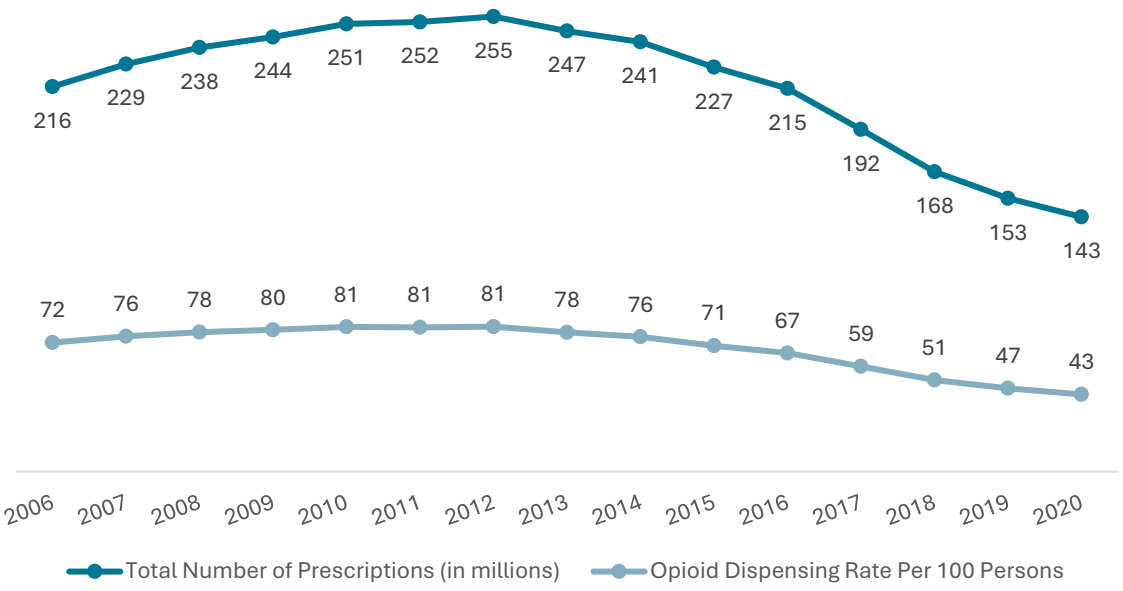


Exhibit 5: Total Opioid Prescriptions Dispensed and Opioid Dispensing Rate per 100 People. Source: CDC

1 Yong, R. Jason et al., PAIN: February 2022 - Volume 163 - Issue 2 - p e328-e332
2 Brigham and Women's Hospital. (2021, April 20).
3 Coherent Market Insights
4 The Centers for Disease Control and Prevention (CDC)
5 Vowles KE et al., Pain. 2015 Apr;156(4):569-576.

Appendix

Income Statement	FY2023 A	FY2024 A	FY2025 E	FY2026 E	FY2027 E	FY2028 E
Net sales	2,230,520.0	5,210,031.0	2,691,210.0	-	35,120,376.0	48,961,129.1
Cost of sales	-	-	-	-	(10,536,112.8)	(12,240,282.3)
Gross profit	**2,230,520.0**	**5,210,031.0**	**2,691,210.0**	**-**	**24,584,263.2**	**36,720,846.8**
Operating expenses						
General and Administrative Expenses	(5,361,234.0)	(4,720,728.0)	(5,428,837.2)	(5,971,720.9)	(12,292,131.6)	(12,240,282.3)
Marketing Expense	-	-	-	-	(4,214,445.1)	(5,875,335.5)
Research and Development	(7,587,473.0)	(7,219,437.0)	(7,941,380.7)	(9,529,656.8)	(8,780,094.0)	(4,896,112.9)
EBITDA	**(10,718,187.0)**	**(6,730,134.0)**	**(10,679,007.9)**	**(15,501,377.8)**	**(702,407.5)**	**13,709,116.2**
Depreciation and amortization expenses	-	-	(6,743.1)	(13,471.2)	(66,151.7)	(192,274.0)
Other income/ (expense)						
License Agreement Payments	-	-	-	-	-	-
EBIT	**(10,718,187.0)**	**(6,730,134.0)**	**(10,685,751.0)**	**(15,514,848.9)**	**(768,559.2)**	**13,516,842.2**
Interest Income	-	-	-	-	-	-
Interest Expense	(353,945.0)	(1,290,444.0)	(36,199.2)	(36,199.2)	(36,199.2)	(36,199.2)
Profit before exceptional items, extraordinary items and tax	**(11,072,132.0)**	**(8,020,578.0)**	**(10,721,950.2)**	**(15,551,048.1)**	**(804,758.4)**	**13,480,643.0**
Issuance cost for convertible notes	-	-	-	-	-	-
Change in fair value of derivative liabilities	-	-	9,063.0	-	-	-
Loss on issuance of convertible notes	-	-	-			
Change in fair value of convertible notes	146,479.0	-	-	-	-	-
Issuance of liability classified warrants	-	16,292.0	-	-	-	-
Change in fair value of liability classified warrants	283,958.0	-	-	-	-	-
Loss on debt conversion	-	-	-			
Other income and expense, net	15,420.0	17,277.0	36,890.0	-	-	-
Profit before tax from continuing operations	**(10,626,275.0)**	**(7,987,009.0)**	**(10,675,997.2)**	**(15,551,048.1)**	**(804,758.4)**	**13,480,643.0**
Income tax (expense) benefit	-	-	-	-	-	(2,830,935.0)
Net earnings including noncontrolling interests	**(10,626,275.0)**	**(7,987,009.0)**	**(10,675,997.2)**	**(15,551,048.1)**	**(804,758.4)**	**10,649,708.0**

Exhibit 6: Income Statement. Source: Diamond Equity Research

Risks

- **Clinical Development Risk -** ENSC is a pharmaceutical company in a clinical stage. The emergence of any undesirable side effects in test subjects could hinder approvals. Their success hinges on PF614 and PF614 product candidates, both of which are in the trial stages.

- **Regulatory Risk -** As a pharmaceutical company, ENSC has to obtain approvals from multiple authorities under various legislations and compliance. The regulatory processes are also lengthy, and approval is uncertain. There is also a risk of regulatory bodies disagreeing with their product regulatory plans. The FDA fast-track designation might not provide the intended ease if products fall short in compliance. They are also subject to lawsuits from future collaborators and any infringements on intellectual property.

- **Finance and Dilution Risk -** ENSC has a limited operating history and incurred significant losses. This risk is exacerbated by the possibility of encountering unforeseen losses in their trials. Furthermore, there is the risk involved in the listing and volatility of their common stock. With their requirement for substantial funding, raising capital by issue of common stock under market value would adversely affect dilution, their market price, their operations, and their control over their technologies and product candidates. There is also a risk of their stocks being delisted from NASDAQ or their warrants' trading being discontinued in the OTC Pink Open Market.

- **Strategic/Competitive Risk -** Growth depends on the product candidates' success in commercialization, discovery, and development. Failure to do so would significantly hinder growth. Furthermore, competitive products could diminish or eliminate commercialization potential. Reliance on third parties for trials, manufacturing, and development also poses a significant risk. Lastly, even if product candidates receive regulatory approval, the possibility of failing in market acceptance poses a risk to successful commercialization.

- **Intellectual Property Risk -** It is important to note risks related to securing, protecting, and updating of intellectual property since any failures would deter operational success and could have major competitive implications. There are also Litigation risks related to the infringement of intellectual parties' intellectual property rights when they challenge the validity of ENSC patents or other intellectual property. ENSC could also be involved in litigation to protect their own intellectual property and other risks related to protection, like the lack of protection under the Hatch-Waxman Amendments through the extension of the patent term.

Disclosures

Diamond Equity Research, LLC has created and distributed this report. This report is based on information we consider reliable, including the subject of the report. This report does not explicitly or implicitly affirm that the information contained within this document is accurate and/or comprehensive, and as such should not be relied on in such a capacity. All information contained within this report is subject to change without any formal or other notice provided. Diamond Equity Research, LLC is not a FINRA registered broker/dealer or investment adviser and does not provide investment banking services and follows customary internal trading procedures pending the release of the report found on disclosure page.

This document is not produced in conjunction with a security offering and is not an offering to purchase securities. This report does not consider individual circumstances and does not take into consideration individual investor preferences. Recipients of this report should consult professionals around their personal situation, including taxation. Statements within this report may constitute forward-looking statements, these statements involve many risk factors and general uncertainties around the business, industry, and macroeconomic environment. Investors need to be aware of the high degree of risk in micro capitalization equities, including the complete potential loss of their investment.

Diamond Equity Research LLC is being compensated by Ensysce Biosciences, Inc. for producing research materials regarding Ensysce Biosciences Inc., and its securities, which is meant to subsidize the high cost of creating the report and monitoring the security, however, the views in the report reflect that of Diamond Equity Research. All payments are received upfront and are billed for an annual or semi-annual research engagement. As of 08/15/2025, the issuer paid us $105,000 for our services, which commenced 10/10/2022 and includes an annual fee of $35,000 for the first two years and quarterly upfront payments of $8,750 for the following year. Diamond Equity Research LLC may be compensated for non-research related services, including presenting at Diamond Equity Research investment conferences, press releases and other additional services. The non-research related service cost is dependent on the company, but usually do not exceed $5,000. The issuer has not paid us for non-research related services as of 08/15/2025. Issuers are not required to engage us for these additional services. Additional fees may have accrued since then.

Diamond Equity Research, LLC is not a registered broker dealer and does not conduct investment banking or receive commission sharing revenue arrangements related to the subject company of the report. The price per share and trading volume of subject company and companies referenced in this report may fluctuate and Diamond Equity Research, LLC is not liable for these inherent market fluctuations. The past performance of this investment is not indicative of the future performance, no returns are guaranteed, and a loss of capital may occur. Certain transactions, such as those involving futures, options, and other derivatives, can result in substantial risk and are not suitable for all investors.

Photocopying, duplicating, or otherwise altering or distributing Diamond Equity Research, LLC reports is prohibited without explicit written permission. This report is disseminated primarily electronically and is made available to all recipients. Additional information is available upon request. For further questions, please contact research@diamondequityresearch.com