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Zacks Small-Cap Research

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Ensysce Biosciences (ENSC-NASDAQ)

ENSC: ***Continuing to make progress toward tackling the opioid addiction crisis.***

ENSC is a clinical stage pharmaceutical company dedicated to bringing a novel opioid to the market. Using discounted cash flow analysis and a discount rate of 25%, we arrive at a valuation for ENSC of $23.00.

Current Price (02/28/22)	$1.12
Valuation	**$23.00**

OUTLOOK

Ensysce Biosciences is committed to finding a solution to the opioid crisis plaguing the US and other developed countries around the world. Through their proprietary TAAP technology Ensysce are in the process of receiving approval for an abuse-resistant yet still pain-relieving opioid.

The main drug program, PF614, continues to move through the approval process, with a recent study affirming the safety profile of the drug.

SUMMARY DATA

52-Week High	**$16.00**
52-Week Low	**$1.05**
One-Year Return (%)	**-91.80**
Beta	**-0.55**
Average Daily Volume (sh)	**310,615**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$27**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**25**
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 2021 Estimate	**N/A**
P/E using 2022 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	0.8E	2.7E
2022	1.1E	1.2E	1.2E	0.9E	4.6E
2023	1.0E	0.7E	0.7E	0.5E	2.9E
2024	2.2E	20E	25E	35E	82.2E

Earnings per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	N/A	N/A	-0.71A	0.09E	-0.62E
2022	-0.16E	-0.16E	-0.20E	-0.22E	-0.74E
2023	-0.25E	-0.27E	-0.30E	-0.37E	-1.19E
2024	-0.20E	0.00E	0.02E	0.06E	0.08E

Latest Developments

Ensysce Biosciences continues to make progress toward their goal of helping attack the crippling opioid crisis currently facing humanity. Their TAAP and MPAR technologies, which are detailed below in this report, continue to move along the FDA pipeline toward the ultimate goal of getting these potentially life-saving products into the market. We continue to be encouraged by the actions of management at Ensysce and believe investors with a higher risk tolerance looking for a potentially game-changing investment that also has the added benefit of providing a solution to one of the great social problems facing society today should take a look at Ensysce. The investment case is detailed below and we wanted to give some updates on the company's continued progress that we believe continues to bolster the investment case for Ensysce:

- December 2021—The company announced that it had enrolled the first patients in the Phase I study of MPAR, which is designed to reduce opioid overdose. The company's Chief Medical Officer, Dr. William Schmidt, said, "The clinical data coming from this trial will guide our MPAR drug product development. We intend to use the data to provide the building blocks to design a second trial at the end of 2022 to fully demonstrate the lifesaving overdose protection of our MPAR technology."

- January 2022—Ensysce announced that it had successfully completed Part A of the previously announced study. This part of the trial evaluated three dose levels of PF614, the company's drug abuse resistance program described in detail below, while other participants received OxyContin at comparable dose levels. The safety study was deemed successful, with full results expected in the first quarter of 2022, and allows Ensysce to continue to the second phase of the 2-part study, a bioequivalence study, the results of which are expected by the end of the second quarter of 2022.

- January 2022—the first dosing in bioequivalence study of PF614 compared to OxyContin was announced.

- February 2022—announced the appointment of Lee Rauch to Ensysce's Board of Directors. We view this as a positive addition, with Ms. Rauch bringing company building experience combined with merger and acquisition and financing qualifications to the company.

These developments, in our view, continue to bolster the case for investing in Ensysce Biosciences and further supports our enthusiasm for a company pursuing a technology meant to tackle the scourge of opioid addiction. We are anxiously awaiting results from the ongoing trials described and, at this point, are expecting those results to reveal more positive results—further bolstering the investment case for Ensysce.

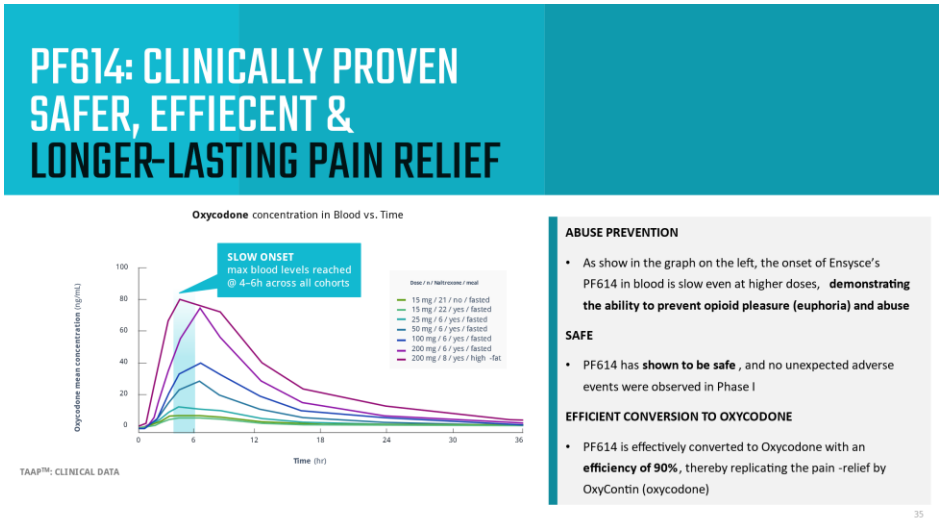
The Science

The technology under the TAAP platform is designed to release effective opioid drugs only when exposed to specific physiological conditions—in this case specifically when the drug is ingested and exposed to the digestive enzyme trypsin. The company's proprietary technology prevents abuse through a two-step internal trypsin-activation process. Their prodrugs are chemically stable molecules that are activated only when administered orally. Due to the activating enzyme of trypsin not being present in blood or saliva, the drug cannot be activated through injection, chewing or snorting. This is in contrast to many other opioid products marketed having, or in late-stage clinical development for, "abuse-resistance". These products often use extended-release formulations, which are still prone to abuse by crushing, chewing or extracting and injecting the drug for an immediate release of active opioid to achieve a rapid euphoric rush.

Ensysce claims that TAAP and MPAR limit all forms of drug abuse and is adaptable to most prescription drugs having the potential for abuse—potentially extending the market beyond opioids.

PF614

PF614 is the company's lead abuse resistant drug program. Ensysce has prioritized this program due to the crisis of oxycodone described above and the urgency to find a more abuse-resistant form of therapy. It is a chemically modified, extended-release oxycodone-derivative which releases clinically effective oxycodone only when exposed to trypsin, which is enzyme found in the digestion system. Importantly, the abuse-resistance provided by PF614 is designed to be unaffected by simple physical manipulation such as extraction, chewing or crushing.



Source: Enscysce Biosciences-https://ensysce.com/-Accessed-February 28, 2022

As seen in the above table, PF614 has completed the Phase I trial. This occurred in 2016-2017 and was conducted by PRA Health Studies—Early Development Services in Lenexa, Kansas. PRA Health Studies is one of the leading early-stage clinical trial providers in the world, with over 13,000 employees in over 80 countries and averaging over 150 early phase studies every year. The Phase I clinical study evaluated PF164 for safety and pharmacokinetics (the study of the time course of drug absorption) of oxycodone release in 64 healthy subjects at various levels of dosing. PF 614 was compared to the effects of OxyContin, which is a brand name of an oxycodone hydrochloride extended-release tablet. The study found that the pharmacokinetic data for PF614 demonstrated an

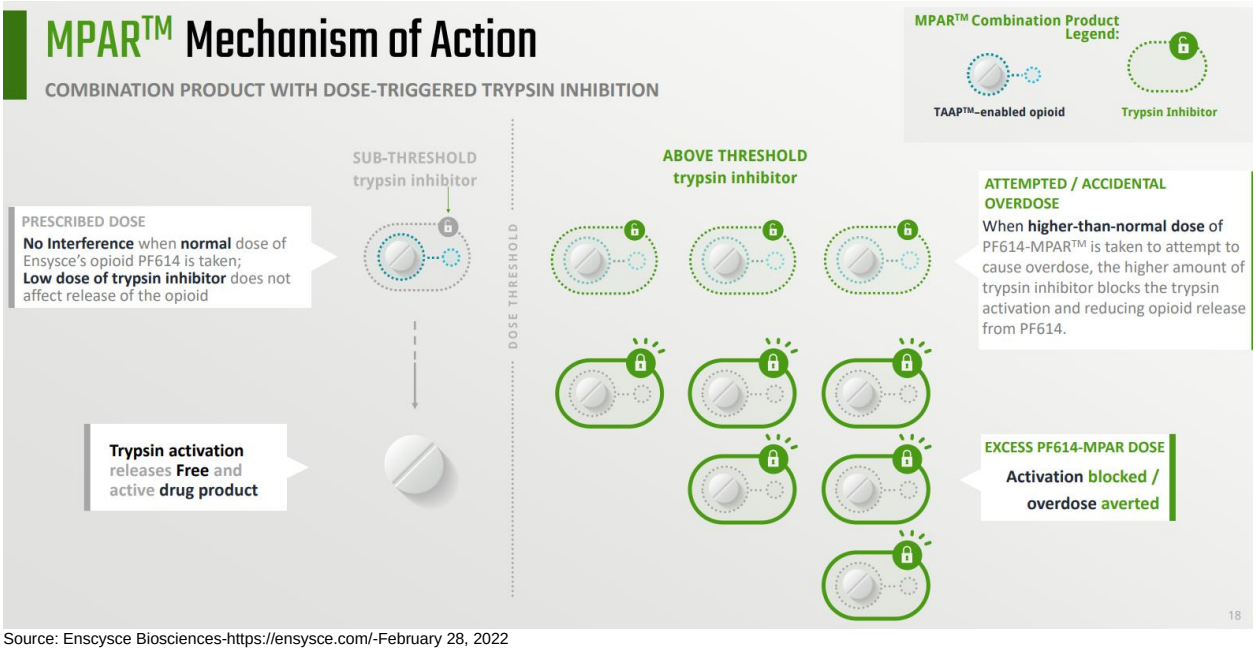
extended-release profile for oxycodone and a 12-hour half-life that will provide a true twice-a-day dosing regimen. Importantly, PF614 was well tolerated and showed no unexpected safety concerns.

Following the results from the Phase I study, in January 2018 the FDA granted Fast Track designation for development of PF614. According to the FDA, the Fast Track designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially better than available therapy. A drug with the Fast Track designation is eligible for more frequent meetings with the FDA, more frequent written communication from the FDA and eligibility for Accelerated Approval and Priority Review—if relevant criteria are met.[1]

PF614 is currently undergoing additional studies-described above. Additionally, two human abuse liability studies will be initiated in the near future with a goal of understanding the tendency for drug abusers to like the effects achieved from taking PF614 either orally or nasally as compared to a competing product such as crushed OxyContin.

PF614-MPAR

MPAR (Multi-Pill Abuse Resistant) is a proprietary technology developed by Ensysce that protects patients from overdosing. It provides a trypsin inhibitor that limits the activation with increasing ingestion of the product. A small amount of MPAR is added to each TAAP product and does not affect the opioid release if taken as prescribed. Conversely, if the prescription is not followed, either intentionally or accidentally, MPAR provides protection through a trypsin inhibitor that block the activation and release of the opioid. Encysce has initiated a Phase I study of PF614-MPAR to assess the pharmacokinetics of oxycodone when PF614 is administered alone and with MPAR.



Source: Enscysce Biosciences-https://ensysce.com/-February 28, 2022

[1] FDA-https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

The Investment Case

Ensysce Biosciences is the California-based pharmaceutical company behind these programs that could provide hope for the millions impacted by opioid addiction and potential addiction. The company, as it now formed, is a result of a merger with a SPAC (Special Purpose Acquisition Company) in January 2021 and closing at the end of June 2021. While this changed the ownership structure, the management that had been shepherding the drug candidates through the approval process remained in place. As mentioned above, Ensysce's major drug candidate, PF614, recently started the Phase 2 trial process where the company aims to demonstrate the correlation between PF614 and Oxycontin and how Ensysce can begin to make the drug available to the general public. As mentioned, the drug has been granted Fast Track status by the FDA, which is clearly a positive, but, as with most pharmaceutical companies at this stage, funding the research, development and testing until the drug can be sold commercially is the major hurdle.

At the present time, Ensysce Biosciences looks to us to be in a better funding position than many other clinical-stage pharmaceutical companies. As noted above, Ensysce has been granted funding by governmental agencies that has helped them to this point and should continue to aid the process through the end of 2022. In our view, Ensysce's funding position has improved greatly in the past year and gives us more confidence in being able to make it to the commercialization stage. For example, Ensysce's cash position has improved from the end of 2020 when the company reported a mere $194,000 in cash on the balance sheet, while by September of 2021 $6.8 million was posted to the balance sheet. A large part of that increase is attributable to a convertible note financing Ensysce undertook in September for $15 million, with $5 million paying out in September and the other $10 million being distributed in November 2021. The notes, carrying an interest rate of 5%, have a maturity day of 21 months from the September issuance and can be converted to Ensysce common stock at $5.87. The notes also include warrants that are exercisable for five years following the date of issuance at a price of $7.63.

The other major current potential source of funding comes from a financing deal with GEM Yield Bahamas Limited, which could provide Ensysce with up to $60 million over the next three years. The share subscription facility allows Ensysce to control the timing and amount of drawdown of the funds, which will be determined by the closing price of ENSC during the 30 trading days prior to the issuance of a draw. The GEM agreement, as it is known, is limited by the above-described convertible note issuance.

It is our opinion that the funding situation at Ensysce is good and will get better. If the PF614 drug continues to proceed through the trial process successfully, as we expect it to, we believe the interest in the company will grow and the funding opportunities will greatly increase. An additional aspect of the Ensysce business that we believe could make it more attractive to investors as PF614 gains traction is the explosion by financers interest in so-called ESG (environmental, social and governance) investing. With no hard guidelines available to define what exactly can fit into the ESG category, providing crucial pain relief equivalent to OxyContin without having the ability to make that drug into an addictive substance that has caused hundreds of thousands of deaths seems to us that it would fit will within an ESG-designated portfolio.

Risks

- Ensysce has sustained substantial financial losses and will continue to lose money for at least the next couple of years—being unable to obtain further funding would likely lead to ENSC ceasing to be a viable company.

- If Ensysce is unable to obtain FDA approval for PF 614 the company's ability to produce revenue would be severely limited.

- Competitors coming up with a similar product sooner than expected would likely result in reduced market share.
- The cost of defending patents around the world could become onerous and hinder eventual profitability.
- Employee count will have to rise to meet the demand and being unable to find the appropriate number of qualified employees would have detrimental effect on Ensysce.
- If the FDA withdraws Fast Track status for PF614 the approval process would likely take substantially longer.
- Doctors may be resistant to prescribing PF614.
- Manufacturing of oxycodone is subject to annual quotas by the federal government, which could result in limited sales.

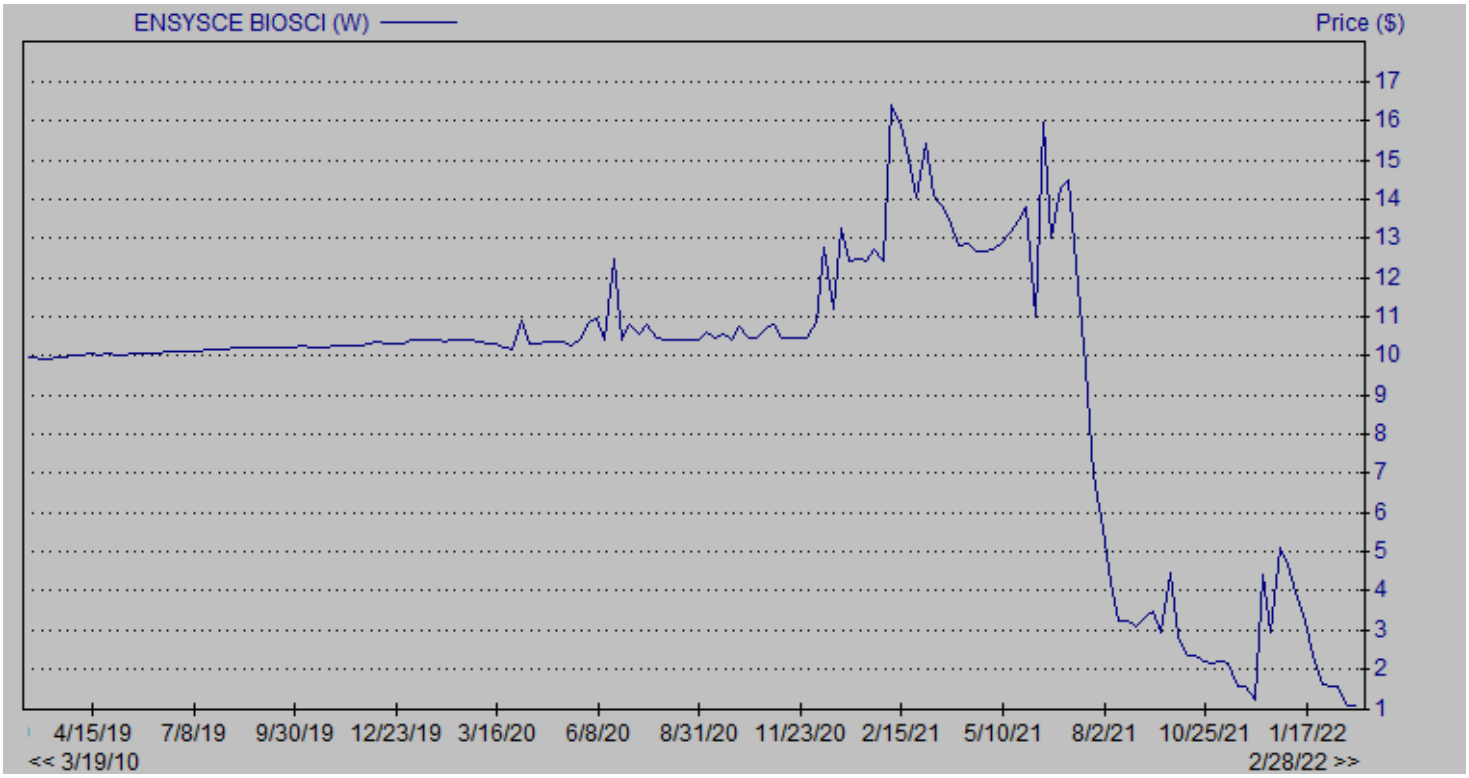
PROJECTED INCOME STATEMENT

Ensysce Biosciences

Income Statement and projections

		9/2020A	12/2021E	12/2022E	12/2023E	12/2024E
Income						
	Federal Grants	1,200,816	2,695,091	4,600,000	2,900,000	2,200,000
	Sales	0	0	0	0	80,000,000
Operating Expenses						
	COGS	0	0	0	0	(14,800,000)
	R&D	(1,714,635)	(2,000,000)	(23,400,000)	(30,700,000)	(21,200,000)
Other	Sales/Marketing	0	0	(4,900,000)	(13,600,000)	(36,200,000)
	Admin/general	(16,372,976)	(17,500,000)	(2,200,000)	(3,100,000)	(6,800,000)
	Interest	(1,258,161)	(1,258,161)	0	0	0
	Other nonrecurring	3,258,161	325,748	0	0	0
Gain/loss		(17,199,474)	(19,337,322)	(25,900,000)	(44,500,000)	3,200,000
Shares		24,255,786	30,942,208	34,942,208	37,442,208	37,816,630
Per share		($0.71)	($0.57)	($0.74)	($1.19)	$0.08

HISTORICAL STOCK PRICE



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