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Ensysce Biosciences (ENSC-NASDAQ)

ENSC: ***ENSC announces 1Q earnings and reiterates positive trial results in the fight against opioid addiction.***

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 $11.00.

Current Price (05/16/22)	$0.64
Valuation	**$11.00**

OUTLOOK

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

Operating results for 3/22 were roughly in line with expectations and provided no cause for concern about the continuation of the approval process. The highlight was a reiteration of positive trial results for the company's signature treatments.

SUMMARY DATA

52-Week High	**$16.00**
52-Week Low	**$0.64**
One-Year Return (%)	**-95.10**
Beta	**-0.53**
Average Daily Volume (sh)	**762,749**
Shares Outstanding (mil)	**35**
Market Capitalization ($mil)	**$22**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**27**
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 2022 Estimate	**-0.8**
P/E using 2023 Estimate	**-0.6**
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	1.0E	1.2E	0.9E	3.7E
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	-0.39A	-0.71A	0.45A	-1.48A
2022	-0.06A	-0.21E	-0.22E	-0.24E	-0.73E
2023	-0.25E	-0.27E	-0.25E	-0.26E	-1.03E
2024	-0.10E	0.50E	0.55E	0.77E	1.72E

Latest Developments

Ensysce Biosciences released 1Q earnings results and a business update—the highlights are following:

- **ENSC** reported a 1Q 2022 loss of $0.06 per share—roughly in line with our expectations.
- **Cash –** Cash and cash equivalents were $8.4 million as of March 31, 2022, as compared to just over $12 million at year end. In the fourth quarter of 2021. Cash used in operating activities in 1Q 2002 totaled $3.4 million.
- **Federal Grants –** Funding under federal grants was $0.6 million for the first quarter of 2022 compared to $0.25 million in the comparable year ago quarter.
- **Research & Development Expenses –** R&D expenses were $3.1 million for the first quarter of 20225 compared to $0.3 million in the same period a year ago. According to management, increases for the quarter were primarily the result of increased external research and development costs related to the clinical programs for PF614 and PF614-MPAR™.
- **General & Administrative Expenses –** G&A expenses were $2.3 million for the first quarter of 2022 compared to $0.5 million for the same period a year ago. Management notes the quarterly increase reflects increased costs from operating as a public company.
- **Net Income (Loss) –** Net loss for the first quarter was $1.0 million compared to net loss of $0.9 million for the comparable year ago period.
- **ENSC** announced clinical trial results from trial PF614-102 that confirmed the safety and longer-lasting profile of PF614 versus Oxycontin.
    - The company is currently analyzing the bioequivalence data from the study, which should be available by the end of 2Q 2022.
- **ENSC** also announced initial results from trial PF614-MPAR-101, which provided the first human data showing the potential for overdose protection with MPAR.
    - The data showed how the combination product PF614-MPAR could reduce the trypsin activation (see below picture for a more detailed look) and reduce the release of oxycodone in a simulated overdose situation.
        - The data also demonstrated the PF 614 in the systemic circulation did not covert to oxycodone.
        - The study is continuing to enroll additional subjects, with results expected by the end of 3Q 2022.

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.

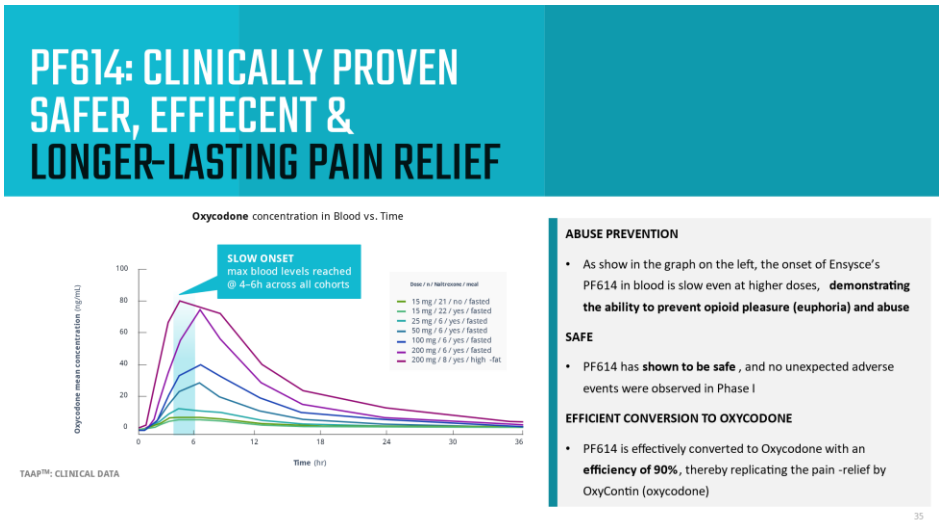
The Science

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. The 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 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-April 1, 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

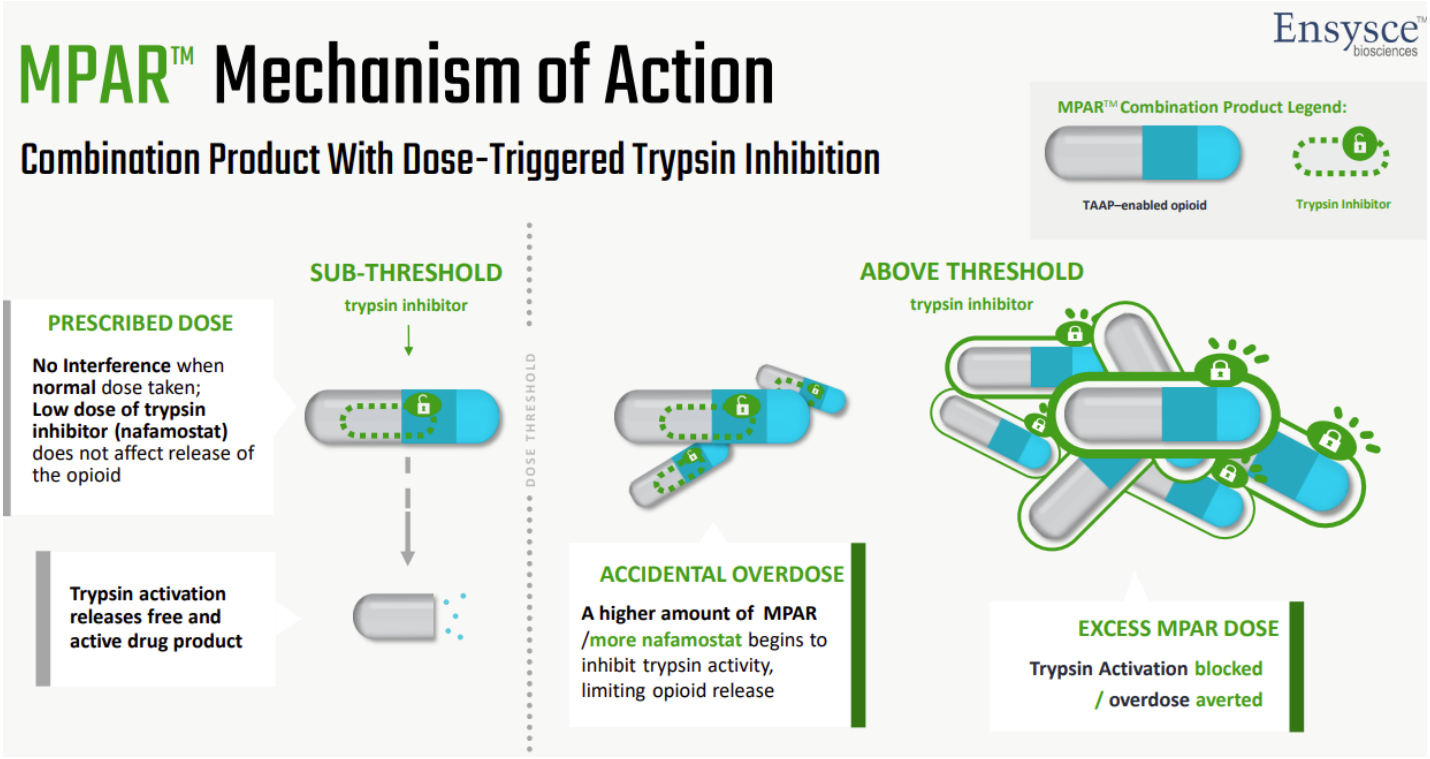
compared to the effects of OxyContin, which is a brand name of an oxycodone hydrochloride extended-release tablet. The study found that the pharmacokinetic data for PF614 demonstrated an extended-release profile for oxycodone and a 12-hour half-life that will provide a true twice-a-day dosing regimen. 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/- May 17, 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, is currently in 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 December of 2021 $12.3 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.

Valuation

Through analyzing potential future revenues and the potential for approval, we arrive at a valuation for Enscyce Biosciences (ENSC) of $11.00, which is roughly half of the discounted cash flow valuation we arrive at due to the current market environment where risk-taking by investors appears to be declining. Valuing a company like Ensysce Biosciences is challenging because there have

been few pharmaceutical companies that have the potential to solve what's been called by every recent US President a crisis. Although the current price doesn't reflect it, we believe we are conservative in our estimates and also recognize the risks that exist with the industry and within any specific drug approval process. Obviously, the valuation of Ensysce hinges on the approval of the PF614 drug by the FDA and subsequent commercialization. Ensysce may be able to use its proprietary TAAP technology with other drugs that have the potential for abuse, but the demand for those drugs would likely be much less and the continued interest of the investing community would likely wain in our view, bringing the future viability of Ensysce into question. As with many clinical-stage pharmaceutical companies, in our view, Ensysce comes down to a zero or one type of binary outcome—PF614 continued along the testing process and gets approved and commercialized in 2024 (currently projected time frame) and Ensysce becomes quite valuable as either a stand-alone company or an acquisition target, but if there is some unforeseen problem that derails the PF614 approval process, it would be hard for us to justify Ensysce as an investment beyond that point.

Needless to say, we believe, and the evidence to this point proves, that PF614 will be approved and that is what our valuation is based on. The global oxycodone market in 2021 is estimated by Future Market Insights to be $4.6 billion, while the US is estimated to have a market of $1.85 billion. Both of those numbers are forecasted by Future Market Insights to grow by 4.8% per year through at least 2031. And we would note here, as part of our conservative analysis, that we believe that number would grow at a faster rate if the hesitancy currently seen due to the addictive qualities of oxycodone was overcome with the approval of PF614.

Due to the binary nature of the potential outcomes and the inherent risk that comes with bringing a new drug to market, we are using a higher than usual discount rate of 25% in the valuation of Ensysce using the cash flow to the firm model. We agree with Ensysce's estimates that show them launching PF614 into the commercial market space in 2024 and achieving a modest 4% market share of the oxycodone market in that year. PF614 will then grow market share to a terminal rate of 50% by 2029. Again, these seems conservative to us—what doctor is going to be proscribing an addictive opioid when an equivalent non-addictive opioid is available? However, although there is no clear competitor to this technology that we have been able to find, a competing product could come on the scene and cut into Ensysce's market share—justifying a more conservative approach. It is important to note, however, that Ensysce currently holds patents on the PF614 and PF614-MPAR technologies that are due to expire between 2030 and 2032, which is one reason we hold the top market share of the US market to 50%. Also, that is only considering the US market, if we move to the global market, then the maximum market share we model for PF614 is 20%. With margins on oxycodone products around the 84% mark and declining research and development costs after the approval of PF614, although sales and marketing costs rise substantially, we project Ensysce will turn a profit of around $3 million in 2024, with that profitability rising to break the $1 billion mark in 2029.

Using all of that information in a discounted cash flow model, while also recognizing that a firm interested in acquiring Enscyse would likely use a similar model and add and acquisition premium, we calculate a valuation of ENSC at $22.00 per share, which we then discount by 50% due to the risk-off nature of investors at the time of this valuation, to arrive at a current valuation of $11.00. We believe the recent market price of ENSC of less than a dollar a share severely undervalues Ensysce due to multiple factors including: a sharp selloff associated with the closing of the acquisition by the SPAC, the market not recognizing the potential that PF614 has to change the narrative surrounding the opioid crisis, and the recent overall biotech downturn due to risk aversion increasing by investors. Although we believe strongly that ENSC is undervalued, it is also a higher-risk investment with some, although certainly not all, of the risk lined out below. We believe that ENSC has excellent potential and would be a good investment to investigate for an investor willing to take a little higher risk.

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.

Financials

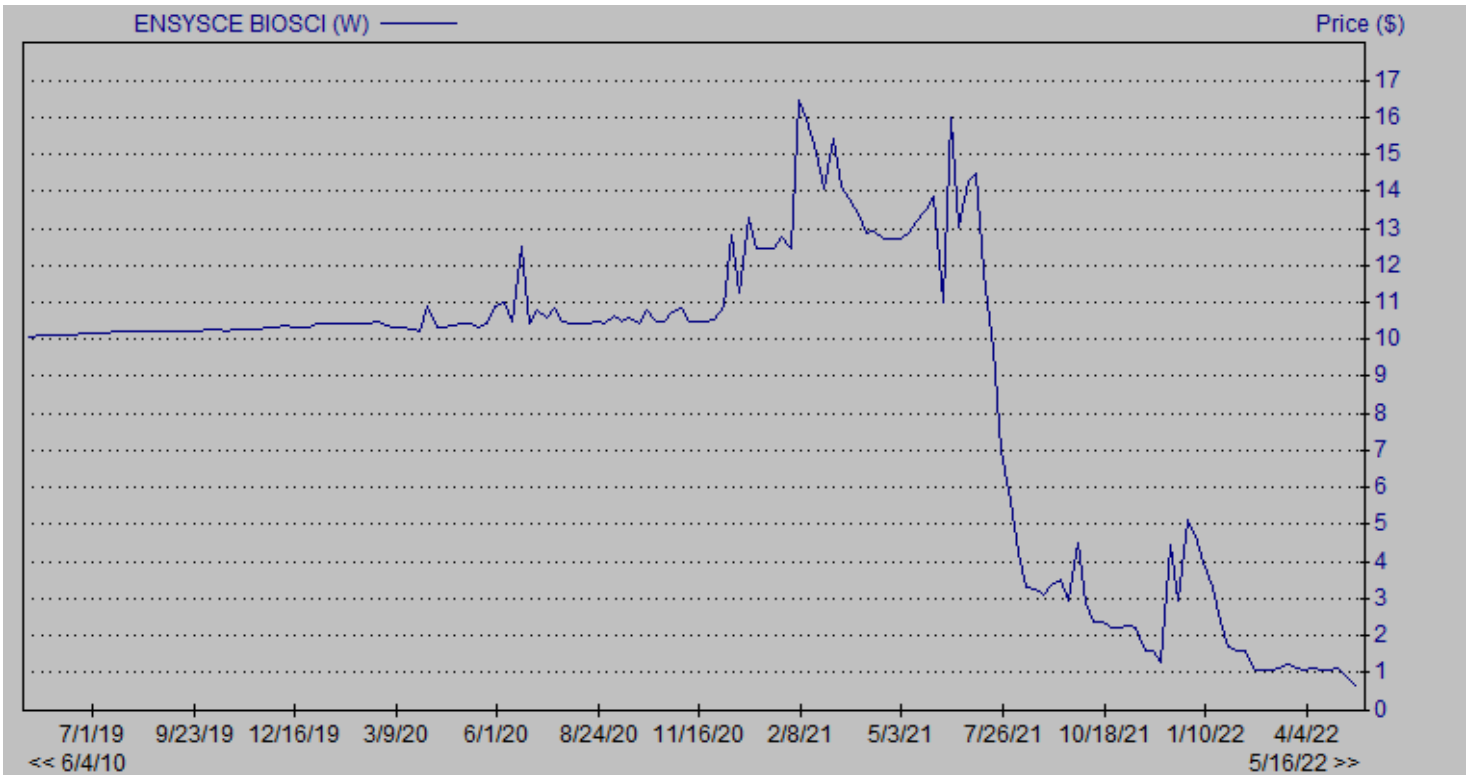
Ensysce Biosciences

Income Statement and Balance Sheet

		(3 mths) 12/2021A	03/2022A	12/2022E	12/2023E	12/2024E	12/2025E
Income							
	Federal Grants	1,635,292	603,098	4,600,000	2,900,000	2,200,000	0
	Sales	0	0	0	0	80,000,000	254,500,000
Operating Expenses							
	COGS	0	0	0	0	(12,800,000)	(40,720,000)
	R&D	(2,187,850)	(3,140,096)	(23,400,000)	(30,700,000)	(21,200,000)	(16,100,000)
Other	Sales/Marketing	0	0	(4,900,000)	(13,600,000)	(36,200,000)	(54,700,000)
	Admin/general/other	(9,484,566)	(2,265,806)	(2,200,000)	(3,100,000)	(6,800,000)	(7,500,000)
	Adjustments to net income	(802,926)	3,136,118	0	0	0	0
Gain/loss		(10,840,050)	(1,666,686)	(21,000,000)	(30,900,000)	54,200,000	230,900,000
Shares		24,089,000	27,287,618	28,651,999	30,084,599	31,588,829	33,168,270
Per share		($0.45)	($0.06)	($0.73)	($1.03)	$1.72	$6.96

		12/2021A	03/2022A	2022E	2023E	2024E	2025E
Assets							
	Cash	12,264,736	8,440,952	12,877,973	13,521,871	14,197,965	14,907,863
	Other	4,152,613	3,930,540	4,360,244	4,578,256	4,807,169	5,047,527
Total Assets		16,417,349	12,371,492	17,238,216	18,100,127	19,005,134	19,955,390
Liabilities							
	Accounts Payable	301,104	959,630	310,137	319,441	329,024	338,895
	Other liabilities	16,180,562	7,842,279	16,665,979	17,165,958	17,680,937	18,211,365
Long-term liabilities		8,093,741	2,458,310	8,336,553	8,586,650	8,844,249	9,109,577
Total liabilities		24,575,407	11,260,219	25,312,669	26,072,049	26,854,211	27,659,837
Shareholder deficit		(8,158,058)	1,111,273	(8,074,453)	(7,971,922)	(7,849,077)	(7,704,447)
Total liabilities and shareholder equity		16,417,349	12,371,492	17,238,216	18,100,127	19,005,134	19,955,390

HISTORICAL STOCK PRICE



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