Initiation Report

ENSYSCE BIOSCIENCES, INC.

Ensysce Biosciences, Inc. – Containing Prescription Drug Abuse Epidemic with Innovative Technology Platforms

Ensysce Biosciences, Inc. (NASDAQ: ENSC)

Share Price: $0.91

Valuation: $5.70

Ensysce™ biosciences

Key Statistics

52 Week Range	$0.97-$140.00
Avg. Volume (3 months)	995,500
Shares Outstanding	5.23M
Market Capitalization	$4.76M
EV/Revenue	n/a
Cash Balance*	$8.60M
Analyst Coverage	3

***Cash balance as of September 2022 (inclusive of public offering)**

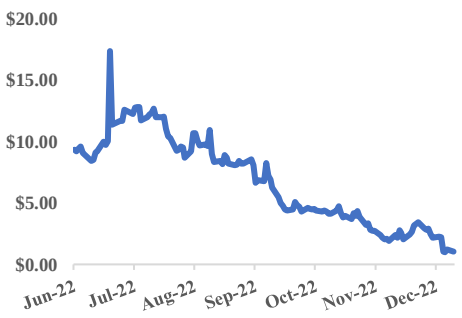
Revenue (in $mm)

Dec - FY	2021A	2022E	2023E
1Q	0.25	0.60	0.85
2Q	0.44	0.21	0.98
3Q	1.20	0.28	1.10
4Q	1.64	2.12	0.97
FY	3.53	3.21	3.90

EPS (in $)

Dec – FY	2021A	2022E	2023E
1Q	(1.20)	(1.22)	(0.65)
2Q	(1.17)	(4.71)	(0.73)
3Q	(14.15)	(5.13)	(1.06)
4Q	(9.00)	(1.67)	(1.19)
FY	(29.64)	(12.34)	(3.63)

Stock Price Chart



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Investment Highlights

- **Unique and Extensible Technology Platform -** Focusing on chemistry and innovation, Ensysce Biosciences has developed a differentiated technology platform that can potentially enhance the delivery mechanism of drugs that are susceptible to abuse and overdose. Trypsin Activated Abuse Protection (TAAP™) platform allows the creation of a prodrug that remains chemically inert until exposed to Trypsin, an enzyme only present in the small intestine, thus preventing abuse. Multi-Pill Abuse Resistance (MPAR™) platform complements the TAAP™ by providing an extra layer of protection by inhibiting overdose. The platform allows the creation of a combination product (TAAP prodrug + Nafamostat) that leverages the TAAPs mechanism of action to reduce the potential of any overdose. Nafamostat is an enzyme inhibitor that has the potential to suppress the trypsin activation process. Both these platform technologies are controllable (aids in the creation of both IR and ER formulations) with vast applicability that can be applied to numerous drug classes to create much safer and more efficient alternatives.

- **Addressing the Opioid Crisis -** The opioid crisis continues to remain a public health emergency in the United States, with an increasing number of overdose-related deaths. More than half a million people died due to opioid overdose in the United States during the past decades involving both prescription and illicit opioids. A total of 142.8 million opioid prescriptions were written in 2020, and an estimated 20% of those were accounted for by oxycodone. The addictive and easily manipulative nature of these drugs remains one of the key reasons for this crisis. Opioid analgesics with abuse-deterrent formulations (ADFs) have gained interest in the past five to six years, with FDA encouraging its development to combat the opioid crisis. This has given rise to abuse-deterrent opioids that cannot be manipulated or abused through other means of administration that are not recommended for use. Many of these drug products have either been discontinued or had modest success due to their inability to be fully abuse resistant. There remains a larger unmet need in the treatment of chronic or acute pain, given the lack of safer alternatives. Ensysce, with its innovative and novel approach, can potentially address this high unmet need. In 2021 2.2 million prescriptions of Oxycodone ER were written, leading to sales of approximately $1.3 billion.

- **Favorable Clinical Results and Long Patent Life -** The primary focus remains to advance its lead pipeline candidate, PF614, and follow-on candidate PF614 MPAR™ through clinical development and towards FDA approval. PF614, A TAAP™ prodrug of oxycodone, is currently in the final stages of the Phase 2 clinical trial. Developed on the back of the TAAP™ platform, PF614 has exhibited slower onset, longer half-life, and a good safety profile in the clinical trial results announced to date. Furthermore, the recently announced topline results of the Human Abuse Potential (intranasal) study indicated the favorable abuse-deterrent ability of the drug. PF614-MPAR™ is currently being evaluated in phase 1 clinical trials in healthy patients. The topline results from the MPAR™ trial indicated that nafamostat reduced the trypsin activation at higher dosages, thus inhibiting oxycodone release and absorption even at higher than prescribed dosage levels. Both these drugs carry a long patent life that is expected to last until 2032 and can be extended by up to five years under the provision of the Hatch-Waxman Act.

- **Valuation –** Using a risk-adjusted DCF with a discount rate of 15%, we have incorporated the company's two lead drug candidates, PF614 and PF614-MPAR™, in our valuation estimates, thus yielding a valuation of $29.89 million or $5.70 per share contingent on successful execution by the company.

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™).

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.

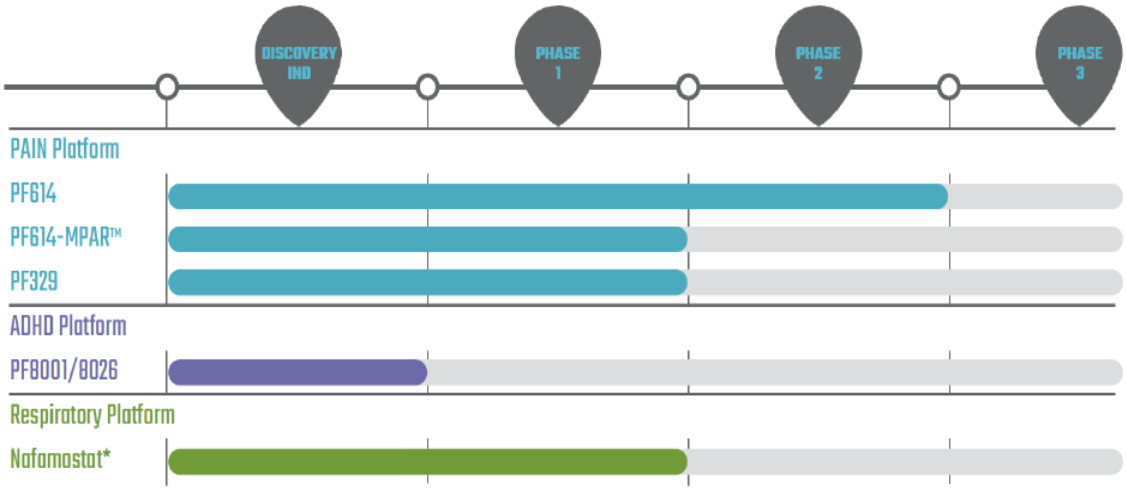

Exhibit 1: Ensysce Product Pipeline. Source: Ensysce Investor Presentation

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 (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.

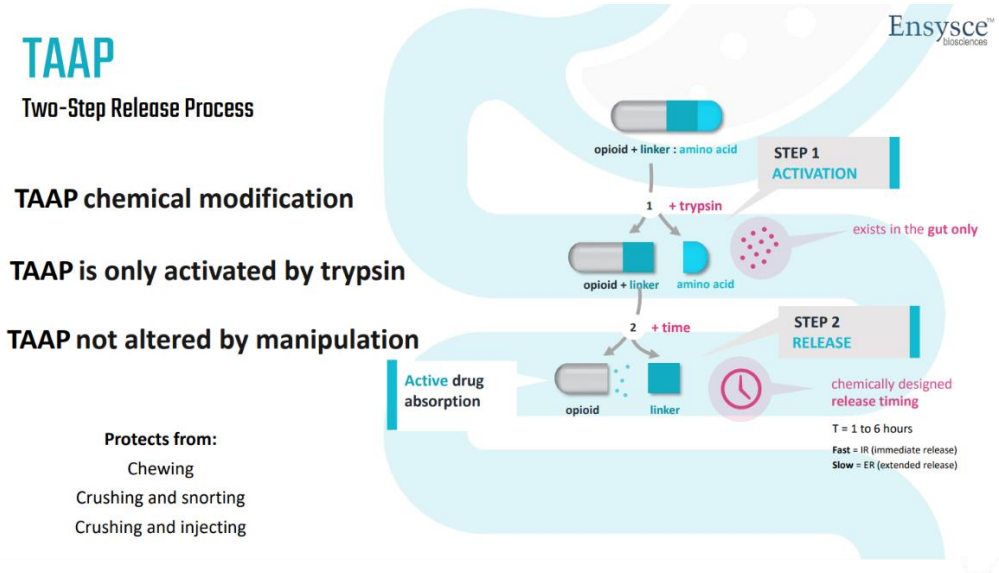

Exhibit 2: TAAP™ Mechanism of Action (MoA). Source: Company Filings

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.

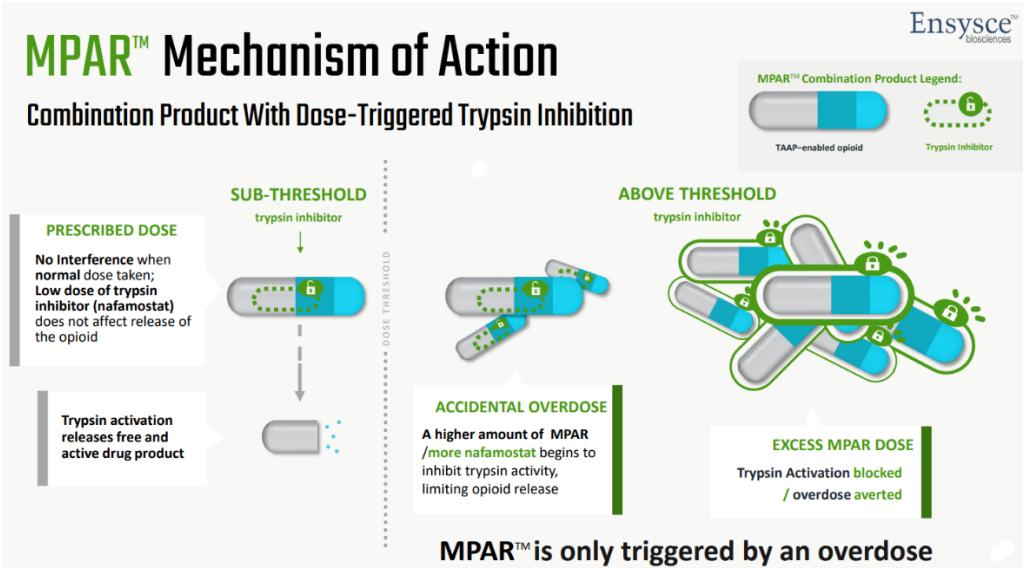

Exhibit 3: MPAR™ Mechanism of Action (MoA). Source: Company Filings

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

TAAP™ and MPAR™ technology platforms, when applied to numerous drug cases, hold the potential to enhance the 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.

Pre-Clinical Design, Safety, and Efficacy Assessment of PF614

A series of *in vitro* and *in vivo* assessments were conducted to determine the safety, efficacy, and abuse potential of PF614, a novel BIO-MD™ prodrug of oxycodone, and support its introduction to clinical trials. Plasma and cerebral spinal fluid levels of oxycodone (OC) were evaluated following in vivo IV administration of PF614 in rats. *In vitro* extraction of OC from PF614 was explored to determine the release of OC from the prodrug. Further non-clinical studies were carried out to determine the clinical safety of PF614. The *in-vitro* studies included multiple genetic toxicology assays (Ames test, comet, and micronucleus assay) to assess the potential for induction of any genetic mutations, DNA, and chromosomal damage. The *in-vivo* studies included rat and dog GLP 14-day toxicology studies and dog safety pharmacology studies to evaluate the safety profile of PF614.

PF614 was found to be stable with *in vitro* exposure to human plasma, saliva, and liver microsomes and also at all room temperature conditions with ⩾90 percent remaining as intact prodrug, indicating the reduced potential for IV or nasal abuse.[1] The *in vivo* studies indicated CNS penetration was 83-fold lower when compared to OC and exhibited 6.5-fold reduced potency as a μ-opioid agonist. Oral PF614 administration in dogs indicated sustained release with reduced Cmax (peak plasma concentration) and delayed Tmax (time to reach Cmax). Unlike existing opioid formulations, the extended-release profile of PF614 cannot be accelerated by chewing or ex vivo extraction to pharmacologically active substances.[1] The prodrug prevents any euphoria and abuse while achieving similar efficacy in pain relief as demonstrated by the existing opioid formulation.

The pre-clinical trials indicated PF614 had no toxicological effects and favourable safety profiles with reduced potential for abuse

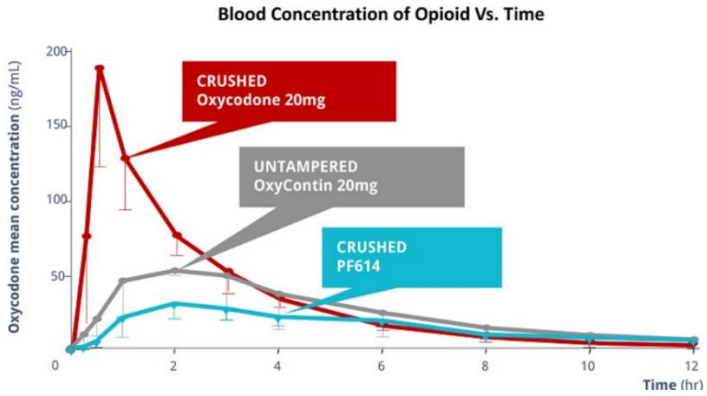

Exhibit 4: Pre-clinical data in dogs comparing Ensysce's opioid against the current opioid OxyContin demonstrated that Ensysce could prevent opioid abuse while other formulations cannot. Source: Company Filings

Further non-clinical safety assessment indicated PF614, and its fragments tested negative in Ames assay and also resulted in negative *in-vivo* comet and micronucleus assays, thus indicating that PF614 carries no significant toxicological effects implying the substance has a low probability of genetic toxicity and is non-genotoxic. PF614 neither induced statistically significant increases in micronucleated PCEs nor was it cytotoxic to bone marrow at 10, 40/25, and 175/50 mg/kg/day

[1] Kirkpatrick DL et al., J Opioid Manag. 2017 Jan/Feb;13(1):39-49

oral gavage doses in both male and female rats.[2] The toxicity data indicated both 25 and 18mg/kg dosages were well tolerated in rats and dogs at 14 days with favorable safety profiles.[2]

The initial *in vivo* and *in vitro* assessment and the later non-clinical safety assessment indicated PF614's robust safety profile and high abuse deterrent potential with similar efficacy as achieved in other approved Oxycodone formulations.

PF614-101 Phase 1 Clinical Study Design and Trial Results

Ensysce Biosciences has completed the phase 1 PF614-101 single ascending dose (SAD) study assessing the safety and pharmacokinetics (PK) of PF614 in comparison to OxyContin, an oxycodone hydrochloride extended-release formulation. The study was a randomized, single-center study recruiting 64 patients in 6 cohorts, with eight healthy patients in each cohort in addition to 16 patients in cohort 7. Each cohort had two study arms, wherein subjects received a single dose of PF614 (n=6) or OxyContin (n=2) orally with and without naltrexone blockade. The initial dosage level for PF614 was 15mg, while the comparable dosage level for OxyContin was 10mg. The single ascending dose study also compared the release of oxycodone from PF614 under both fasted and fed conditions. The primary outcome measure was safety and evaluation of adverse events, while the secondary outcome measures included pharmacokinetics data evaluation.

Studies showed that PF614 can achieve more efficient and longer-lasting pain relief than OxyContin (even when crushed) under a true twice-a-day dosing regimen

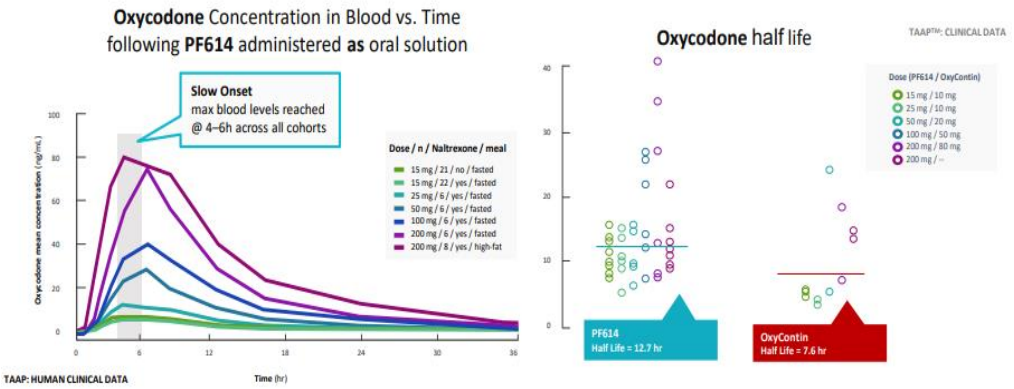

Exhibit 5: PF614 SAD Study Pharmacokinetics. Source: Company Filings

The study was well tolerated and reported a good safety profile with slow onset and longer half-life than OxyContin. The Cmax levels reached at 4h to 6h time intervals across all cohorts. Further, the shape of plasma concentration vs. time curve of oxycodone was similar following the administration of OxyContin (oxycodone extended-release) and PF614. PF614 was shown to have a true BID dosing regimen with a 12.7hr half-life compared to just 7.6hr for OxyContin. Of the 64 patients enrolled, 23 experienced treatment-emergent adverse events or TEAEs. Most of the adverse events were reported to be either mild or moderate-grade events with no discontinuations due to study drug-related adverse events. PF614 was found to be well tolerated by up to 200 mg in healthy subjects.

[2] Joshi PS et al., Regul Toxicol Pharmacol. 2019 Nov; 108:104433.

PF614-101 phase 1 trial was successful, providing a clear demonstration of PF614's safety and efficient delivery of OC with long-lasting pain relief. Additionally, it provided significantly important PK data (such as potency ratio), allowing the company to advance the clinical trial. PF614-101 phase 1 trial was followed by PF614-102 phase 1b randomized, 2-part multiple ascending oral dose Study (Part a) and a comparative bioavailability/bioequivalence and food effect study (Part b).

PF614-102 phase 1b Clinical Trial Design, Safety, and Efficacy

The underlying study was recently concluded and enrolled 84 patients evaluating the pharmacokinetics and safety of multiple ascending oral doses (MAD) of PF614 and the bioavailability/bioequivalence (BE) of single oral doses of PF614 relative to OxyContin in healthy adult subjects. Patients enrolled in part A (MAD study) were administered twice a day with either PF614 (n=18) or OxyContin (n=6) for 5 days. Part B (BE study) was 4-way crossover design enrolling 60 patients who were administered PF614 100mg or OxyContin 40mg under fasted and fed conditions (4 arms - two fed and two fasted). The primary and secondary endpoints included safety, tolerability, pharmacokinetics, bioequivalence, and bioavailability.

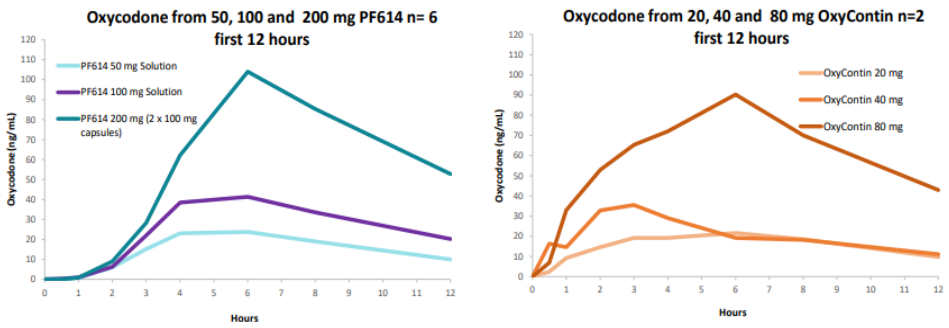

Exhibit 6: PF614 MAD Study Pharmacokinetics. Source: Company Filings

The clinical results from the two-part MAD study confirmed the favorable results obtained from the previous phase 1 SAD trial. Part A of the MAD study indicated PF614 indicated slower onset with Cmax reaching 4hrs - 6hrs, while for the comparable OxyContin dosage levels, Cmax reached 2hrs - 6hrs. The study also suggested a longer-lasting half-life as compared to that of OxyContin. PF614, as a therapeutic option for pain management, further exhibited low variability in oxycodone absorption between fed and fasted conditions compared to other commercial products.

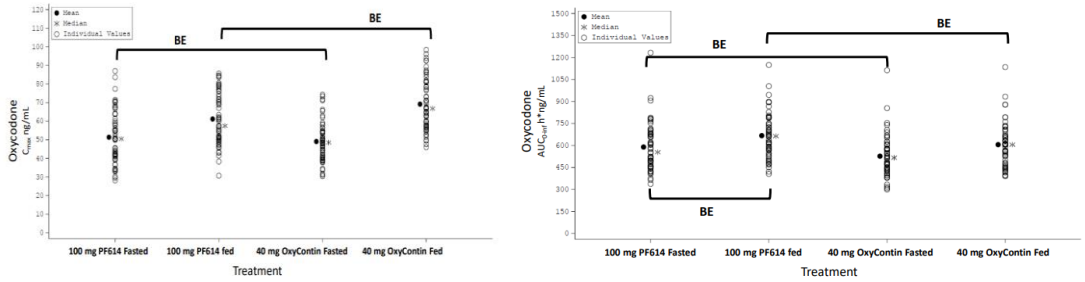

Exhibit 7: PF614 MAD Study Bioequivalence - Cmax and AUC(0-inf). Source: Company Filings

In the BE study arm (Part B of the MAD study), PK and bioavailability of Oxycodone from PF614 and OxyContin at 100 mg and 40 mg, respectively, were determined under fed and fasted conditions, thus ascertaining bioequivalence. PF614 produced oxycodone mean Cmax (peak plasma concentration) of 49.56 and 59.72 ng/mL under fed or fasted conditions, respectively, after a median of 6 hrs. Mean AUCinf under fed or fasted condition was determined at 571 h*ng/mL and 652 h*ng/mL, respectively.

OxyContin 40mg produced mean Cmax (peak plasma concentration) of 67.55 and 47.90 ng/mL under fed or fasted conditions, respectively, after a median of 4.4 hrs. Mean AUC under fed or fasted condition was determined at 510 h*ng/mL and 584 h*ng/mL, respectively. The variability of oxycodone absorption (Cmax and AUC) under PF614 100 mg dosage under fasting versus fed was 20% and 14%, respectively. For PK factors, the comparable 40 mg Oxycontin produced a variability of 41% and 14% under fasting versus fed conditions, respectively, thus indicating higher variability in OxyContin compared to that of PF614 under fasted and fed conditions.

The PF614-102 clinical trial indicated that the oxycodone prodrug met the required FDA bioequivalence acceptance criteria for both AUC and Cmax when compared to OxyContin under both fasted and fed conditions. Further, PF614 achieved approximately similar levels of Cmax at greater tmax and AUC, suggesting delayed onset with more efficient absorption, total exposure, and extended activity of active ingredients compared to OxyContin.

Part A: Table of Adverse Events

	PF614 50 mg n=6 n (%)	OxyContin 20 mg n=2 n (%)	PF614 100 mg n=6 n (%)	OxyContin 40 mg n=2 n (%)	PF614 200 mg n=6 n (%)	OxyContin 80 mg n=2 n (%)
Total subjects with at least 1 TEAE*	2 (33.3)	1 (50.0)	1 (16.7)	1 (50.0)	6 (100.0)	2 (100.0)

Part B: Table of Adverse Events

	PF614 fasted 100 mg n=58 n (%)	OxyContin fasted 40 mg n=59 n (%)	PF614 fed 100 mg n=58 n (%)	OxyContin fed 40 mg n=58 n (%)
Total subjects with at least 1 TEAE*	14 (24.1)	12 (20.3)	12 (20.7)	9 (15.9)

* **Treatment Emergent Adverse Events**: Vertigo, Photophobia, Nausea, Constipation, Diarrhea, Vomiting Urinary Tract infection, Tooth fracture, Decreased appetite, Dizziness, Headache, Depressed mood, Rhinorrhoea, Dermatitis, fall

Exhibit 8: PF614 MAD Study TEAEs. Source: Company Filings

Both the arms of the study (Part A and B) were well tolerated, with limited and opioid-related adverse events, most of which were mild and moderate. The safety profile exhibited by PF614 was similar to that of OxyContin, with no test article serious adverse events recorded. The phase 1b trial reconfirms the PF614's PK and safety profile shown in the previous PF614 clinical trial.

Advancing the Clinical Trial Toward Phase 3

The company is currently in the final stages of Phase 2 clinical trial, with trial results expected to be reported by the first half of 2023. Ensysce had previously initiated two human abuse potential (HAP) studies via intranasal administration and oral administration in May 2022 and September

2022, respectively. The HAP study via intranasal administration (PF614-103) is completed, with results awaited, while the study via oral administration (PF614-104) is active.

Both the HAP (PF614-103 and PF614-104) studies are double-blinded, placebo and active-controlled crossover studies evaluating the abuse potential of PF614 compared with immediate-release oxycodone and placebo through two prevalent abused routes of oxycodone abuse (oral and intranasal).

PF614-103's Clinical Trial Design

The 3-way crossover study enrolled 27 participants, evaluating the abuse potential and pharmacokinetics of intranasally administered PF614. The participants received PF614 100mg capsules, crushed oxycodone HCI IR 40mg, and placebo powder in a randomized, double-blinded, crossover manner following a fasting period of at least 8 hours. The primary endpoint included peak maximum effect (Emax) for drug liking and Take Drug again VAS, while the secondary endpoints included PK and safety data.

Top-Line Results

The company recently announced the top-line results of the PF614 intranasal HAP study. The study indicates that PF614 powder produced significantly lower peak "drug liking" (Emax) compared to that of fully crushed IR oxycodone (p= 0.0133). Furthermore, in the first-period analysis of initial impressions of each drug, favorable results were observed with significant differences in peak effects (Emax) of "take drug again" between PF614 and IR oxycodone, where PF614 produced only 27% as high an Emax score as crushed IR oxycodone (p<0.0001). The prodrug of oxycodone demonstrated significantly reduced "drug liking" and "take drug again" when compared to IR oxycodone. The statistically significant top-line results speak volumes of PF614's abuse-deterrent ability.

PF614 is currently being evaluated in two human abuse potential study (intranasal and intravenous), the clinical results of which is expected to support the abuse deterrent labelling upon final approval of the drug

PF614-104's Clinical Trial Design

The company is evaluating the abuse potential, safety, and pharmacokinetics of orally administered PF614. With an estimated enrollment of 36 participants, the study will consist of four phases (screening, qualification, treatment, and follow-up visit). Eligible participants will receive five treatments (one per treatment period) in a randomized, double-blind, crossover manner. The primary and secondary endpoints are similar to that of the PF614-103 clinical trial.

The company has progressed with its lead product candidate and is in the final stages of the phase 2 clinical trial. We expect phase 3 analgesic efficacy studies to begin by the second half of 2023. The management believes that the bioequivalence study supports the 505(b)(2) regulatory path for FDA approval allowing the company to leverage third-party clinical studies and results for PF614 approval. The 505(b)(2) regulatory pathway would accrue multiple benefits to the company in terms of lower development risk, lower costs and NCE regulatory exclusivity. Additionally, PF614 is protected by a broad set of patents providing exclusivity till at least 2032.

In addition, the provisions under Hatch-Waxman Act allow another five years of exclusivity in the United States.

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.

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™.

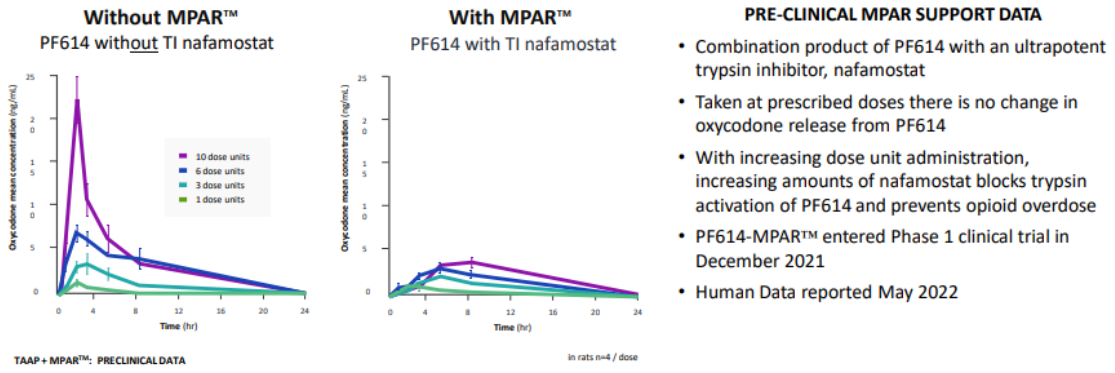

Exhibit 9: PF614-MPAR™ Pre-Clinical Data. Source: ENSC Investor Presentation

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 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™.

MPAR™-101: Phase 1 Clinical Trial Design and Initial Data

PF614-MPAR™ is being assessed in phase 1 randomized, single-dose study since December 2021. PF614(25mg) is administered alone and with nafamostat(10mg) as an immediate-release solution and/or extended-release (ER) capsule formulations to evaluate the pharmacokinetics and safety of the novel combination product in healthy patients. An equal split is expected among the subject sample, planned to compose of 64 volunteers split into 10 cohorts, with each cohort having a 50:50 male-female sample. The primary outcome and secondary measures included the

evaluation of the pharmacokinetics profile (Cmax, Tmax AUC, T1/2), and safety and tolerability profile (TEAES).

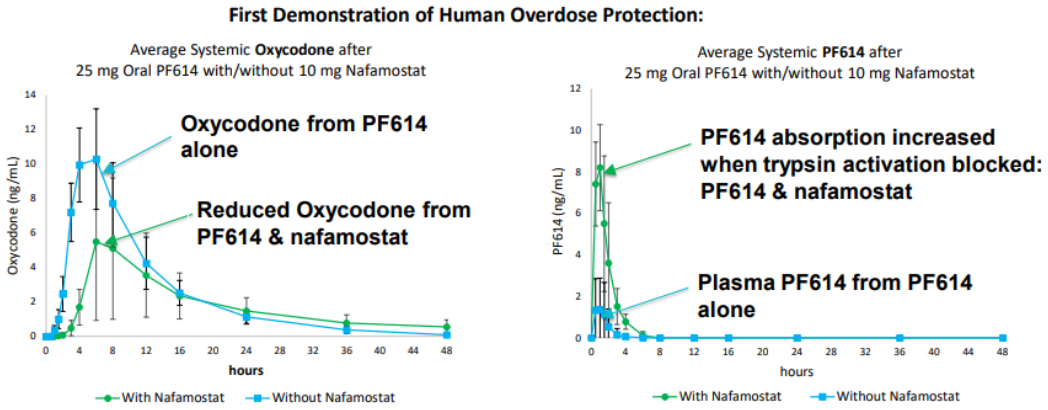

Exhibit 10: PF614-MPAR™ Pre-Clinical Data. Source: ENSC Investor Presentation

Development Plans

The company is progressing well and has successfully completed the clinical portion of the study, which is expected to allow the company to specify an exact ratio of PF614 and nafamostat necessary to provide optimal pain relief with overdose protection. The company is expanding the study and is expected to initiate Part B in 2023 in order to confirm the overdose protection with escalating dose units. Further data readout is expected in December 2022. Additionally, the company has partnered with Quotient Sciences, a drug development and manufacturing accelerator, to support the development of PF614-MPAR™.

Quotient is leveraging its trademarked Translational Pharmaceutics platform in order to arrive at a formulation of PF614-MPAR™ that would permit oxycodone conversion within the prescribed dosage range but reduce the conversion in the event of an overdose. The resultant formulation is expected to yield an optimized composition that would balance the dose and release rate.

Other Pipeline Assets Building Further Upside Optionality

Ensysce Biosciences, Inc. has built a solid foundation within its pain platform program, exhibiting robust clinical trial results. In addition to PF614 and PF614-MPAR™ clinical agents, the company has built a diversified pipeline that includes multiple ADHD and respiratory pipeline candidates.

Nafamostat - Respiratory Agent Currently in Clinical Development

Nafamostat mesylate (Nafamostat), a synthetic serine protease inhibitor with anticoagulant, anti-inflammatory, and mucus-clearing properties, is a potential antiviral agent. Nafamostat (Futhan®, Torii Pharmaceuticals) is an approved pharmaceutical to treat disseminated intravascular coagulation (DIC) and pancreatitis in Japan and has been used clinically since the 1980s.

Multiple clinical and pre-clinical research studies have been published exploring the potential of nafamostat as an antiviral candidate in treating coronavirus by blocking viral entry. The drug's inhibition of TMPRSS2 enzyme activity has been found to suppress membrane fusion between the virus and the human cells, consequently inhibiting viral infection and replication. Nafamostat has been shown to inhibit viral entry in MERS and COVID-19 CoVs, and clinical trials with infusional nafamostat have been initiated in Asia.[3]

Nafamostat has not been approved as an oral, intranasal, or inhalational formulation in any jurisdiction. Ensysce has been previously exploring oral nafamostat in complement to its TAAP™ technology to develop an overdose deterrent for opioid drugs. These studies led to the company's interest in evaluating the oral nafamostat to target SARS-CoV-2.

Promising Pre-Clinical Findings and NAF-101 Clinical Trial

The pre-clinical study included using a human airway epithelial model to evaluate the effects of nafamostat on tissue-level cellular ultrastructure and viral infection kinetics of SARS-CoV-2 lung infection. Evaluation of the pre-clinical study results confirmed the potent anti-viral activity of nafamostat against SARS-CoV-2. This study also demonstrated both the safety and the powerful inhibitory effect of nafamostat when applied apically on human airway epithelia on SARS-CoV-2 genome copy detection.[3]

The preclinical trial was followed by a clinical trial evaluating the safety, tolerability, and pharmacokinetics of oral nafamostat in healthy participants in a three-part study. Part 1 was a single ascending dose study enrolling eight subjects who were administered 50, 100, and 200 mg of nafamostat sequentially on three separate days. Part 2 was a multiple ascending dose study administering 100 mg of nafamostat twice daily to four participants in cohort 1. The second cohort enrolled four participants who were administered 200mg of nafamostat twice daily for five days. The final part 3 of the study was multiple fixed-dose studies to evaluate the safety and tolerability of 200mg oral nafamostat solution administered three times daily to six healthy participants.

The study was well tolerated, and no drug-related adverse events were reported for nafamostat delivered at 200 mg three times daily. Nafamostat was shown to have limited bioavailability at any dose level evaluated up to 200 mg. The company is planning to evaluate oral nafamostat in phase 2 clinical trials in COVID-19 patients.

PF8001 / PF8026: TAAP™ And MPAR™ Amphetamine & TAAP™ Methadone

PF8001/PF8026: Ensysce is extending its proprietary TAAP™ and MPAR™ technologies to improve the safety of ADHD medication. PF8001 and PF8026 utilize the company's proprietary technology to develop ER and IR prodrugs of amphetamine for ADHD. Both candidates are currently in pre-clinical trials.

[3] D. Lynn Kirkpatrick, Jeffrey Millard, bioRxiv 2020.09.16.300483

PF26810: or TAAP™ Methadone utilizes the company's proprietary technologies to develop an ER prodrug of methadone for Opioid Use Disorder (OUD). Methadone is a synthetic opioid agonist used as a pain reliever and for the treatment of drug addiction. Ensysce Biosciences had previously received a multi-year grant from the National Institute on Drug Abuse (NIDA) amounting to $14.5 million to undertake pre-clinical and clinical development of the novel OUD medication. PF26810 is currently being evaluated in pre-clinical trials.

PF8001/PF8026, and PF26810 are the three other drug candidates that can potentially cater to abuse by stimulant drugs, in this case Amphetamines

TAAP™ and MPAR™ technology remain the key asset with a significant potential to generate long-term value for the company's stakeholders. The extensible nature and broad applicability of the proprietary technology have allowed the company to build a diversified pipeline of enhanced and safer drug candidates for the treatment of ADHD, OUD, and chronic or acute pain. Even though the company's primary focus still remains PF614 and PF614 MPAR™, other pipeline candidates (NafamostatS, PF8001/PF8026, and PF26810) provide high upside optionality and longer value creation runway.

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.[4] Furthermore, the total estimated value of lost productivity at approximately $300 billion.[5]

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.[6] A total of 142.81 million prescriptions of opioids were dispensed in the United States in 2020.[7] 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%.[8] Additionally, 187 people die every day from opioid overdose (Rx and illicit).[7] 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.

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

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

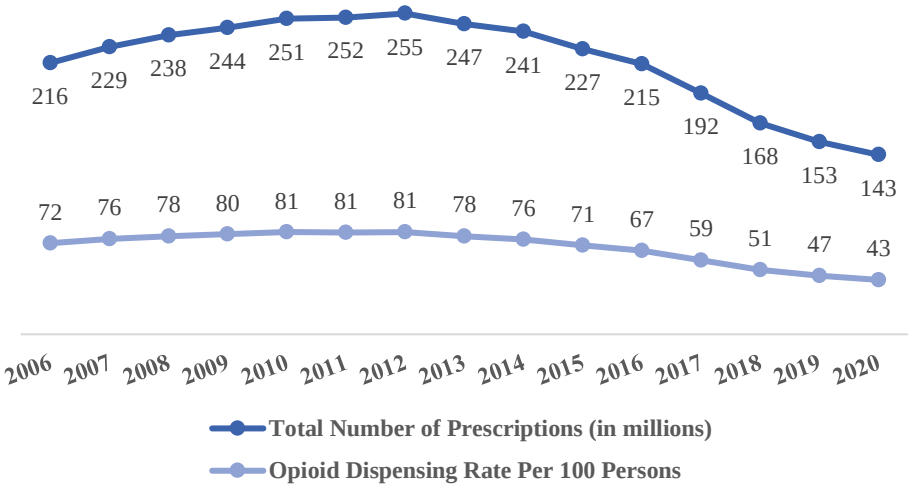

Exhibit 11: Total Opioid Prescriptions Dispensed and Opioid Dispensing Rate per 100 People. Source: CDC

Opioid analgesics with abuse-deterrent formulations (ADFs) have gained interest in the past 5-6 years, with FDA encouraging its development to combat the opioid crisis. Abuse deterrent formulations are not tamper-proof but reduce the possibility of drug abuse through common means of administration that include snorting or injecting. A survey of physician beliefs, behaviors, and psychology relating to ADFs suggested the primary motivator for prescribing ADFs was preventing diversion by family members, not patient-level abuse concerns.[9] Opioid analgesics with ADFs can only be used as directed (as approved uses) and prevents intentional misuse. Additionally, few states have made it mandatory to prescribe abuse-deterrent opioids over non-abuse-deterrent formulations.

Brand Name	Manufacturer	Type of Opioid	Year of Approval	Commercially Available
OxyContin® (reformulated)	Purdue Pharma	Oxycodone	2010	Yes
Targiniq ER™	Purdue Pharma	Oxycodone	2014	No
Embeda®	Pfizer	Morphine	2010	No
Hysingla® ER	Purdue Pharma	Hydrocodone	2015	Yes
MorphaBond™	Daiichi Sankyo	Morphine	2015	No
Xtampza™ ER	Collegium Pharma	Oxycodone	2016	Yes
Troxyca® ER	Pfizer	Oxycodone	2016	No
Arymo® ER	Egalet Corp.	Morphine	2017	No

[9] Dasgupta N et al., Pain Ther. 2022 Mar;11(1):133-151.

Vantrela™ ER	Cephalon, Inc	Hydrocodone	2017	No
RoxyBond™	Protega Pharma	Oxycodone	2017	Yes
Opana® ER (reformulated)	Endo Pharmaceuticals	Oxycodone	2012	No

Exhibit 12: FDA Abuse-deterrent Opioids. Source: Becker WC & Fiellin DA, 2017, Diamond Equity Research

Abuse-deterrent opioids have been found to have limited and modest success, at the same time, multiple ADFs have been withdrawn from the market given their inability to mitigate the risk of overdose. Two FDA-approved ADFs, Troxyca® ER and Vantrela™ ER, have been withdrawn from the market because they can be manipulated despite their potential to deter abuse.[10] Similarly, reformulated Opana® ER, introduced in 2012, was further discontinued in 2017 as it could not meaningfully reduce abuse.

Oxycodone, a strong semisynthetic opioid, remains one of the commonly prescribed medications for the treatment of pain. In 2013, the US accounted for 81.0% of the world's oxycodone consumption. Additionally, 21.4% of total opioid prescriptions, i.e., 53 million oxycodone prescriptions, were dispensed in the same year.[11] A number of opioid medications, including oxycodone, comes in two delivery mechanism, extended release and immediate release, with different active ingredient absorption rate. Ensysce's lead drug candidate PF614 is an extended-release TAAP™ prodrug of oxycodone. In 2021, 2.2 million prescriptions of oxycodone ER were written, generating approximately $1.3 billion in gross U.S. sales. The 2.2 million prescriptions represent the company's immediately serviceable market.[12]

Competitive Overview

The company's lead drug candidate, PF614, is extended release TAAP™ prodrug of oxycodone and is being evaluated in clinical trials. Once approved, it will compete with other extended-release formulations that are FDA approved and are being marketed. Of the five FDA-approved abuse-deterrent oxycodone ER (refer to exhibit 12), only two are currently being marketed, OxyContin, generic versions of OxyContin, and Xtampza ER. Both these drugs employ different abuse-deterrent technologies to counter intentional misuse of the drug. OxyContin remains the largest-selling ER oxycodone in the US in dollar terms and prescriptions volume as well. The total prescriptions written for OxyContin were approximately 1.5 million in 2021, generating a total sale of $0.9 billion.[12] This represented a y-o-y decline of 19% and 20% in dollar sales and prescriptions written, respectively, for OxyContin and authorized generics. At the same time, Collegium reported a 20% growth in prescriptions written in 2021 at 681,000 (representing less than 1% of the overall opioid market). The company generated revenue of $128 million in 2021. Similar levels of growth were reported in 2020, where the prescription written grew from 466,000 in 2019 to 566,000 in 2020.

[10] Kinam Park and Andrew Otte, Annual Review of Biomedical Engineering 2019 21:1, 61-84
[11] DrugAbuse.com
[12] Collegium Pharmaceutical, Inc., Company Filings

Management Overview

Ensysce Biosciences is led by an experienced team with deep expertise and extensive experience in biotech, life sciences, healthcare, and related fields. The management strives to develop a range of new treatments that seek to stem the prescription drug abuse epidemic.

- **D. Lynn Kirkpatrick, Ph.D. - Chief Executive Officer**

  Dr. Lynn Kirkpatrick holds the position of Chief Executive Officer at Ensysce Biosciences. She has over twenty-three years of experience developing novel therapies for diseases with few therapeutic options and unmet needs. She co-founded Ensysce Biosciences and PHusis Therapeutics and has developed three targeted small molecule oncology drugs - from discovery to the clinic. She has a background in medicinal chemistry, pharmacology, drug discovery, and development and is experienced in private and public company fundraising. Dr. Kirkpatrick holds a Ph.D. in Medicinal and Biomedicinal Chemistry from the University of Saskatchewan and a Post Doc in Pharmacology from Yale University School of Medicine.

- **Dr. William K. Schmidt, Ph.D. - Chief Medical Officer**

  Dr. William K. Schmidt serves as the Chief Medical Officer at Ensysce Biosciences. He has over 25 years of pharmaceutical experience, with a special focus on the discovery and development of novel analgesic and narcotic antagonist drugs. His previous roles include serving as a Vice President of Clinical Development for Crystal Genomics (Seoul, South Korea) and its United States subsidiary, CG Pharmaceuticals; Senior Vice President of Development at Limerick BioPharma; Vice President, Clinical Research for Renovis, Inc.; and Vice President, Scientific Affairs, Clinical Research and Development, at Adolor Corporation. Dr. Schmidt received his Bachelor of Arts from the University of California Berkeley and Ph.D. from the University of California - San Francisco.

- **Dave Humphrey - Chief Financial Officer**

  Dave Humphrey holds the position of Chief Financial Officer at Ensysce Biosciences. He has a vast experience in corporate strategy, financial planning & analysis (FP&A), Equity/Debt financing, Mergers & acquisitions, and is a trusted advisor to CEOs and the board of directors at both private and public stage companies. During his previous stint at Senomyx, Inc, where he was the Vice President and Chief Financial Officer, he led a $75 million acquisition, advising the negotiation strategy and merger terms and conditions. Mr. Humphrey graduated with honors in Accountancy from The University of Illinois Urbana-Champaign.

- **Geoff Birkett - Chief Commercial Officer**

  Geoff Birkett holds the position of Chief Commercial Officer at Ensysce Biosciences. He has several decades of medical devices, biotech, and pharmaceutical experience, where

he has held leadership roles in major pharmaceutical companies in the UK, Germany, and the USA. He has launched 7 brands, out of which 5 brands (including Prozac, Seroquel, Zomig, and Nicorette) became the market leaders Mr. Birkett graduated from INSEAD.

- **Linda Pestano - Chief Development Officer**

  Linda Pestano holds the position of Chief Development Officer at Ensysce Biosciences. Mr. Pestano is experienced in the design of pre-clinical programs focused on building IND-enabling data packages for lead candidate compounds intended for the treatment or diagnosis of cancer and inflammatory diseases. She has over sixteen years of pharmaceutical experience and holds a Ph.D. in Immunology from Tufts, Postdoctoral Research at Dana Farber, Harvard Medical School.

- **Richard Wright, MSE, MBA - Chief Business Officer**

  Richard Wright holds the position of Chief Business Officer at Ensysce Biosciences. Richard Wright has held positions in investment banking, venture capital, and intellectual property advisory. Richard has been a strategic advisor to Bangkok Dusit Medical Services, the largest healthcare conglomerate in southeast Asia, focusing on pharmaceutical development and market entry strategies. Richard has an MSE in biotechnology/technology management from the University of Pennsylvania School of Engineering & Applied Sciences and the Wharton School of Business (EMTM) and an MBA from the London School of Economics (TRIUM).

- **Jeffrey Millard, Ph.D. - Chief Operating Officer**

  Jeffrey Millard holds the position of Chief Operating Officer at Ensysce Biosciences. He has both academic and industrial experience in chemistry and pharmaceutical sciences covering all aspects of CMC (chemistry, manufacturing, and controls). He's been directly responsible for the research and IND authoring of more than 7 IND submissions (to both CDER and CBER), IMPDs, and several successful SBIR grant applications. He graduated in Biochemistry/Biology & Philosophy from Rice University and holds a Ph.D. in Pharmaceutical Sciences from The University of Arizona.

- **Dr. Bob Gower - Chair of the Board**

  Dr. Bob Gower is the co-founder and chair of the board at Ensysce Biosciences. He has several decades of experience in the chemical industry, 30 of which were in operational and managerial roles for such companies as Atlantic Richfield, ARCO Chemical, and Lyondell Petrochemical Company. He co-founded Carbon Nanotechnologies, Inc. in 2000, where he developed fullerene carbon nanotubes for multiple applications. He then founded Ensysce Biosciences Inc. in early 2008 with the specific focus of using carbon nanotubes in therapeutic areas. Bob received his Ph.D. from the University of Minnesota.

Financial Positioning

The company currently does not have any source of revenue aside from grants secured from government agencies. The quarterly operating cash burn rate is $3.5 - $4.5 million, estimated based on the past four quarterly financial results. This is expected to increase further as PF614 enters Phase 3 clinical trials and PF614 MPAR™ advances through the clinical phase. We have remained conservative and estimated the operating cash burn for 2023e and 2024e at $25.20 and $29.50 million. We expect FDA approval of PF614 by the second half of 2024 and a commercial launch in 2025.

As on September 30, 2022, the company had a cash balance of $4.50 million and post that, it has also completed a $4.10 million public offering. The company reported a debt balance of $8.94 million as of Q3 2022. ENSC reported an average operating cash burn of $4.6 million in the past four quarters. We believe the current cash balance, in addition to the cash raise, might not provide enough runway to support the company's operating and research activities through 2023, and it might have to arrange additional financing.

Year-end 31 Dec. (in $mm)	2020A	2021A	2022E	2023E	2024E
INCOME STATEMENT					
Revenue	$3.93	$3.53	$3.21	$3.90	$0.00
Gross Profit	$3.93	$3.53	$3.21	$3.90	$0.00
EBITDA	($1.61)	($19.87)	($21.86)	($24.05)	($28.60)
Depreciation & Amortization	($0.00)	($0.00)	$0.00	$0.00	$0.00
Profit Before Tax (PBT)	($0.16)	($29.15)	($23.59)	($25.13)	($29.67)
Profit After Tax (PAT)	$0.06	($29.89)	($24.42)	($25.13)	($29.67)
Basic Shares Outstanding	0.79	1.01	1.98	6.93	17.31
EPS - basic	$0.07	($29.64)	($12.34)	($3.63)	($1.71)
BALANCE SHEET					
Cash and cash equivalents	$0.19	$12.26	$4.71	$6.33	$9.35
Other current assets	$0.15	$3.40	$3.19	$3.24	$3.39
Total current assets	$0.35	$15.66	$7.90	$9.57	$12.74
Non-current assets	$0.00	$0.75	$0.63	$0.63	$0.63
Total Assets	**$0.35**	**$16.42**	**$8.53**	**$10.20**	**$13.37**
Short-term borrowing	$4.94	$12.77	$8.39	$8.39	$8.39
Other current liabilities	$2.07	$3.71	$3.97	$3.87	$5.04
Total current liabilities	$7.01	$16.48	$12.35	$12.26	$13.42
Long-term borrowing	$0.00	$4.44	$1.39	$1.39	$1.39
Other non-current liabilities	$0.00	$3.65	$1.41	$1.41	$1.41
Total liabilities	$7.01	$24.58	$15.16	$15.06	$16.23
Total Equity	($6.66)	($8.16)	($6.63)	($4.86)	($2.86)
Total Liabilities & Equity	**$0.35**	**$16.42**	**$8.53**	**$10.20**	**$13.37**

Exhibit 13: Income Statement Snapshot. Source: Diamond Equity Research

Valuation

We have valued the company using risk adjusted DCF as our preferred methodology. Given that the company's primary focus remains PF614 and PF614 MPAR™, we have incorporated the same in our valuation methodology. Both these drug candidates have long patent life and potentially superior or competitive safety and efficacy profile than the currently approved abuse-deterrent opioids in the market. We have modeled the PF614 and PF614 MPAR™ commercialization in the United States in 2025 and 2027, respectively. In line with the recent guidance from the FDA, the company will pursue PF614 initially for an acute pain indication while continuing the development of PF614 for use in chronic pain.

For PF614, we have forecasted the pricing of the drug and the company's growth on a similar line as achieved by Xtampza ER. Furthermore, we have assumed a probability of success at 55% for PF614 and 30% for PF614 MPAR™. Even though PF614 has to compete with other oxycodone ER, we expect a faster uptake in PF614 MPAR™ due to its abuse-deterrent as well as abuse inhibition mechanism of action. Additionally, the company's technology platforms TAAP™ and MPAR™ have broad applications and can be leveraged to develop and market additional drugs, providing Ensysce with a long growth runway.

Using a discount rate of 15%, our valuation methodology yielded a value of $29.89 million or $5.70 per share, contingent on successful execution by the company.

Drug Candidate	Targeted Disease	Probability of Success	Status	Commercialization Year
PF614	Chronic or Acute Pain	55%	Phase 2	2025e
PF614-MPAR™	Chronic or Acute Pain	30%	Phase 1	2027e

Calculated Equity Value ($mm)	
Enterprise Value	$30.09
- Debt and Preferred Stock	$8.98
+ Cash	$8.50
Net Debt	($0.48)
Equity Value	$29.62

Approaches (in $ mm)	Value	Weight	Wtd. Value (USD)
DCF	$29.62	90%	$26.66
GPCM	$32.25	10%	$3.22
GTM	-	0%	$0.00
Wtd Avg. Equity Value (USD)			**$29.89**
No of Shares Outstanding			**5.23**
Intrinsic Value Per Share			**$5.70**

Company Name	Ticker	Price	Currency	Country	Market Cap.	P/B	P/R&D
Pacira BioSciences, Inc.	PCRX	49.86	USD	USA	2,284.80	3.10x	27.59x
Collegium Pharmaceutical, Inc.	COLL	18.84	USD	USA	632.50	3.00x	113.15x
Mallinckrodt plc	MNKPF	17.25	USD	Ireland	190.98	0.10x	1.21x
KemPharm, Inc,	KMPH	5.57	USD	USA	192.82	1.90x	14.91x
Assertio Holdings, Inc.	ASRT	2.70	USD	USA	130.08	1.00x	-
AcelRx Pharmaceuticals, Inc.	ACRX	1.94	USD	USA	14.29	0.40x	2.72x
Trevena, Inc.	TRVN	0.18	USD	USA	31.31	0.90x	1.85x
Median						**1.00x**	**8.81x**
Mean						**1.49x**	**26.91x**

Exhibit 14: Valuation and Comparable Company Analysis. Source: Diamond Equity Research
*(Market Cap. Values in $mm)

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.

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