UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

Form 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended: December 31, 2021
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission File Number 001-38306

ENSYSCE BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**82-2755287**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
7946 Ivanhoe Avenue, Suite 201 La Jolla, California	**92037**
(Address of principal executive offices)	(Zip Code)

(858) 263-4196
(Registrant's telephone number, including area code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	ENSC	The Nasdaq Stock Market
Warrants, to purchase one share of Common Stock	ENSCW	OTC Pink Open Market

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes ☐No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer ☐
Non-accelerated filer ☒
Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to section 13(a) of the Exchange Act ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐No ☒

Registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and, therefore, cannot calculate the aggregate market value of the voting and non-voting common equity held by non-affiliates as of such date.

Registrant had 29,949,032 shares of common stock outstanding as of March 25, 2022.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant has incorporated by reference into Part III of this report certain portions of its proxy statement for its 2022 Annual Meeting of Shareholders, which is expected to be filed within 120 days after the end of the registrant's fiscal year ended December 31, 2021.

ENSYSCE BIOSCIENCES, INC.

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Risk Factor Summary

Below is a summary of material factors that make an investment in our securities speculative or risky. This summary does not address all of the risks and uncertainties that we face. Discussion of the risks and uncertainties in this summary, as well as other risks and uncertainties that we face, can be found under the section titled "*Risk Factors*" beginning on page 34 of this Annual Report on Form 10-K. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described under the section titled "*Risk Factors*" as part of your evaluation of an investment in our securities:

- We are a clinical-stage pharmaceutical company with a limited operating history and have incurred significant financial losses since our inception and anticipate that we will continue to incur such losses for the foreseeable future.
- We must obtain regulatory approval and fulfill numerous other requirements to be successful.
- We require substantial additional funding.
- The price of our common stock on the Nasdaq and Public Warrants on the OTC Pink Open Market may be volatile.
- The proceeds under the GEM Agreement may be less than anticipated and issuances of common stock pursuant thereto would result in dilution of existing stockholders.
- We depend heavily on the success of PF614 and PF614-MPAR™ product candidates, which are currently in clinical trials, and which may not be successful.
- Due to the significant resources required for the development of our product pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others.
- If we fail to discover, develop and commercialize other product candidates, we may be unable to grow our business.
- If we do not achieve our projected development and commercialization goals within the timeframes we expect, the development and commercialization of our product candidates may be delayed.
- Competitive products may reduce or eliminate potential commercial opportunity for our product candidates.
- Our business could be harmed if we lose the services of our key personnel or if we are unable to hire additional highly qualified employees.
- Government grant awards may not be available to us in the future.
- We currently rely on, and expect to rely on in the future, third parties to conduct our clinical trials.
- We expect to be completely dependent on third parties to manufacture our product candidates.
- We must develop our sales, marketing and distribution capability on our own or through collaborations.
- The regulatory approval processes are lengthy, time-consuming and inherently unpredictable.
- Regulatory authorities may disagree with our regulatory plan for our product candidates.
- Interim topline and preliminary data from our clinical trials may change.
- We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the preclinical and clinical studies necessary.
- Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain.
- We may encounter difficulties enrolling patients in our clinical trials.
- Fast track designation by the FDA for PF614 may not lead to a faster development or regulatory review or approval process and does not assure FDA approval.
- I f the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if such requirements are not as we expect, the approval pathway will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.
- Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.
- Even if any of our product candidates receives regulatory approval, we may fail to achieve the degree of market acceptance necessary for commercial success.
- We are subject to potential product liability lawsuits against us or any of our future collaborators.
- Oxycodone is a Schedule II controlled substance under the federal CSA, and we must comply with the CSA or its state equivalents.

- If we are unable to obtain and maintain patent protection for our products candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates that are similar or identical to our product candidates.
- We may face litigation from third parties claiming that our products or business infringe, misappropriate, or otherwise violate their intellectual property rights, or seeking to challenge the validity of our patents.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property.
- The expiration or loss of patent protection may adversely affect our future revenues and operating earnings.
- We may not be able to obtain protection under the Hatch-Waxman Amendments by extending the patent term.
- We may not be able to protect our intellectual property rights throughout the world.
- We may be subject to claims that we infringed, misappropriated or otherwise violated the intellectual property of a third party, or claiming ownership of what we regard as our own intellectual property.
- Our failure to obtain or maintain our patent protection could result in adverse consequences.
- Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.
- We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.
- Our intellectual property agreements with third parties may be subject to disagreements.
- Intellectual property rights do not necessarily address all potential threats to our business.
- If we do not obtain protection under the Hatch-Waxman Amendments by obtaining data exclusivity, our business may be harmed.
- Cyber-attacks or other failures in our telecommunications or information technology systems, or those of third parties could result in information theft, data corruption and significant disruption of our business.
- Raising additional capital in the public or private equity markets at prices per share below the current market price of our common stock could cause dilution to our stockholders, adversely affect the market price of our common stock, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- Our internal controls over financial reporting currently do not meet all of the standards contemplated by Section 404 of Sarbanes-Oxley Act.
- We identified material weaknesses in our internal control over financial reporting as of December 31, 2021 and 2020.
- The Nasdaq may delist our common stock and/or our Public Warrants may not continue to trade on the OTC Pink Open Market.

GLOSSARY

Definitions:	
2013 Framework	Financial reporting criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013)
2021 Notes	The senior secured convertible promissory notes in the aggregate original principal amount of $15.9 million, sold in two closings on September 24, 2021 and November 5, 2021, respectively, pursuant to the Securities Purchase Agreement entered into on September 24, 2021
2021 Omnibus Incentive Plan	Ensysce Biosciences, Inc. Amended and Restated 2021 Omnibus Incentive Plan
ADFs	Abuse deterrent formulations
ADHD	Attention deficit hyperactivity disorder
Aggregate Limit	Up to $60 million of gross proceeds with respect to the GEM Agreement
ANDA	Abbreviated New Drug Application
API	Active pharmaceutical ingredient
ASC 815	Accounting Standards Codification 815, Derivatives and Hedging
AUC	Area under the concentration time curve
Board	Board of directors of Ensysce, or a committee thereof, as applicable
CARA	Comprehensive Addiction and Recovery Act
CBER	Center for Biologics Evaluation and Research
CDC	Center for Disease Control

Definitions:	
CDER	Center for Drug Evaluation and Research
cGMP	Current Good Manufacturing Practice
CI	Clinical investigation
Cmax	Maximum plasma concentration
CMC	Chemistry, manufacturing, and controls
CMOs	Contract manufacturing organizations
CNS	Central nervous system
Company	Ensysce Biosciences, Inc. and its consolidated subsidiaries
Company's Proxy Statement	Company's proxy statement for the 2022 Annual Meeting of Shareowners
COVID-19	Novel coronavirus disease
Covistat	A clinical stage pharmaceutical company that is developing a compound utilized in the Company's overdose protection program for the treatment of COVID-19 and 79.2%-owned subsidiary of the Company
CROs	Contract research organizations
CSA	Controlled Substances Act
CSOS	Controlled Substance Ordering System
DEA	United States Drug Enforcement Agency
Defendants	The Company and its Chief Executive Officer with respect to *DelMorgan Group, LLC et al. v. Ensysce Biosciences, Inc., et al.*, Los Angeles County Superior Court, Case Number 21 STCV25585
Draw Down Limit	400% of the average daily trading volume for the 30 trading days immediately preceding the date the Company delivers the draw down notice with respect to the GEM Agreement
DSCSA	Title II of the Federal Drug Quality and Security Act of 2013, known as the Drug Supply Chain Security Act
EB	Ensysce Biosciences, Inc. prior to its merger with Signature Acquisition Corp. pursuant to the EB-ST Agreement.
EB-ST Agreement	Agreement and Plan of Merger, dated as of December 28, 2015, by and among Signature, SAQ, and EB
EMA	European Medicines Agency
Ensysce	Ensysce Biosciences Inc.
EPO	European Patent Office
ETASU	Elements to assure a products safe use
EUA	Emergency Use Authorization
Exchange Act	Securities Exchange Act of 1934
FDA	United States Food and Drug Administration
FDC Act	Federal Food, Drug and Cosmetic Act

First Closing Notes	Senior secured convertible promissory notes in the aggregate principal amount of $5.3 million the Company issued to investors at the first closing under the SPA
Former Ensysce	Ensysce Biosciences, Inc., a Delaware corporation, prior to the consummation of the merger with and into Merger Sub
GAAP	Generally Accepted Accounting Principles in the United States of America
GCP	Good Clinical Practices
GEM Agreement	Share Purchase Agreement between the Company, GEM Global, and GYBL, dated as of December 29, 2020, including a Registration Rights Agreement between the same parties and dated as of the same date

Definitions:

GEM Global	GEM Global Yield LLC SCS
GEM Warrants	1,106,108 shares of common stock that may be issued upon the exercise of 1,106,108 warrants issued to GYBL under the terms of the GEM Agreement
GMP	Good Manufacturing Practices
GYBL	GEM Yield Bahamas Limited
Hatch-Waxman Act or Hatch-Waxman Amendments	Drug Price Competition and Patent Term Restoration Act of 1984
HHS	United States Department of Health and Human Services
IMPDs	Investigational Medicinal Product Dossiers
IND	Investigational New Drug
IRB	Institutional Review Board
JOBS Act	Jumpstart Our Business Startups Act of 2012
LACQ	Leisure Acquisition Corp., a Delaware Corporation
Merger	The merger of Merger Sub with and into Former Ensysce, with Former Ensysce continuing as the surviving entity and a wholly owned subsidiary of LACQ, which changed its name to Ensysce Biosciences, Inc. following consummation of the Merger.
Merger Agreement	Agreement and Plan of Merger, dated as of January 31, 2021, by and among LACQ, Merger Sub and Former Ensysce, providing for, among other things, and subject to the terms and conditions therein, a business combination between Former Ensysce and LACQ pursuant to the proposed merger of Merger Sub with and into Former Ensysce, with Former Ensysce surviving the transaction as a wholly-owned subsidiary of LACQ, which changed its name to Ensysce Biosciences, Inc. following consummation of the Merger
Merger Sub	EB Merger Sub, Inc., a Delaware corporation, a wholly-owned subsidiary of LACQ prior to the consummation of the Merger
MPAR Grant	Research and development grant related to the development of its MPAR™ overdose prevention technology awarded to the Company by NIH through NIDA in September 2018
Nasdaq	Nasdaq Stock Market LLC
NCE	New Chemical Entity
NDA	New Drug Application
NIDA	National Institute of Drug Abuse
NIH	National Institutes of Health
NME	New molecular entity
OPM	Option Pricing Method
Orange Book	FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations
OUD Grant	Research and development grant related to the development of its TAAP/MPAR ™ abuse deterrent technology for Opioid Use Disorder awarded to the Company by NIH/NIDA in September 2019
PCT	Patent Cooperation Treaty
PDMA	U.S. Prescription Drug Marketing Act
PK	Pharmacokinetics
Plaintiffs	Del Morgan Group, LLC and Globalist Capital, LLC with respect to *DelMorgan Group, LLC et al. v. Ensysce Biosciences, Inc., et al.*, Los Angeles County Superior Court, Case Number 21 STCV25585
PTA	Patent Term Adjustment

Definitions:

PTE	Patent Term Extension
Public Warrants	The redeemable warrants issued by us and sold as part of the units in the LACQ IPO (whether they were purchased in the LACQ IPO or thereafter in the open market). The Public Warrants are exercisable for an aggregate of approximately 10,000,000 shares of common stock at a purchase price of $11.50 per share
R&D	Research and Development
Recro	Recro Gainesville LLC
Recro Agreement	Manufacturing Agreement, dated September 19, 2019, by and between Recro Gaineville LLC and the Company
REMS	Risk evaluation and mitigation strategy
Resale Registration Statement	Ensysce's Resale Registration Statement filed on August 9, 2021
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SAQ	Signature Acquisition Corp., a wholly-owned subsidiary of Signature
SEC	U.S. Securities and Exchange Commission
Second Closing Notes	Senior secured convertible promissory notes in the aggregate principal amount of $10.6 million the Company issued to investors at the second closing under the SPA
SEC Statement	The statement released by the SEC on April 12, 2021, entitled "Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies"
Securities	Common stock and warrants issued to Plaintiffs in satisfaction of its advisory fee with respect to *DelMorgan Group, LLC et al. v. Ensysce Biosciences, Inc., et al.,* Los Angeles County Superior Court, Case Number 21 STCV25585
Securities Act	Securities Act of 1933
Signature	Signature Therapeutics Inc.
SPA	Securities Purchase Agreement, dated as of September 24, 2021, by and between Ensysce and the institutional investors party thereto
SPACs	Special Purpose Acquisition Companies
SUPPORT Act	Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act
TAAP	Trypsin Activated Abuse Protection

TEAEs	Treatment-emergent adverse events
USPTO	United States Patent and Trademark Office

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K includes statements that express Ensysce's opinions, expectations, beliefs, plans, objectives, assumptions, or projections regarding future events or future results and therefore are, or may be deemed to be, "forward-looking statements." These forward-looking statements can generally be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "seeks," "projects," "intends," "plans," "may," "will," or "should" or, in each case, their negative or other variations or comparable terminology. These forward-looking statements include all matters that are not historical facts. They appear in a number of places throughout this Annual Report on Form 10-K and include statements regarding our intentions, beliefs or current expectations concerning, among other things, results of operations, financial condition, liquidity, prospects, growth, strategies and the markets in which Ensysce operates. Such forward-looking statements are based on available current market material and management's expectations, beliefs and forecasts concerning future events impacting Ensysce. Factors that may impact such forward-looking statements include:

- the risk that Ensysce's lead product candidates PF614 and PF614-MPAR™ may not be successful in limiting or impeding abuse, overdose, or misuse or providing additional safety upon commercialization;

- reliance by Ensysce on third-party contract research organizations, or CROs, for its research and development activities and clinical trials;
- the need for substantial additional funding to complete the development and commercialization of Ensysce's product candidates;
- the risk that Ensysce's clinical trials may fail to replicate positive results from earlier preclinical studies or clinical trials conducted by Ensysce or third parties;
- the risk that the potential product candidates that Ensysce develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all;
- the risk that clinical trials may not confirm any safety, potency, or other product characteristics described or assumed in this Annual Report on Form 10-K;
- the risk that Ensysce will be unable to successfully market or gain market acceptance of its product candidates;
- the risk that Ensysce's product candidates may not be beneficial to patients or successfully commercialized;
- the risk that Ensysce has overestimated the size of the target market, patients' willingness to try new therapies, and the willingness of physicians to prescribe these therapies;
- effects of competition;
- the risk that third parties on which Ensysce depends for laboratory, clinical development, manufacturing, and other critical services will fail to perform satisfactorily;
- the risk that Ensysce's business, operations, clinical development plans and timelines, and supply chain could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic;
- the risk that Ensysce will be unable to obtain and maintain sufficient intellectual property protection for its investigational products or will infringe the intellectual property protection of others;
- the loss of key members of Ensysce's management team;
- changes in Ensysce's regulatory environment;
- Ensysce's need for additional financing to fund its operations and research and development;
- the ability to attract and retain key scientific, medical, commercial, or management personnel;
- changes in Ensysce's industry;
- Ensysce's ability to remediate any material weaknesses or maintain effective internal controls over financial reporting;
- the risk that our common stock will be suspended from trading on Nasdaq;
- the ability to meet and maintain applicable listing standards of the Nasdaq; and
- other factors disclosed in this Annual Report on Form 10-K

The forward-looking statements contained in this Annual Report on Form 10-K are based on Ensysce's current expectations and beliefs concerning future developments and their potential effects Ensysce. There can be no assurance that future developments affecting Ensysce will be those that Ensysce has anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Ensysce's control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading "*Risk Factors.*" Should one or more of these risks or uncertainties materialize, or should any of the assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Moreover, the occurrence of the events described in the "*Risk Factors*" section and elsewhere in this Annual Report on Form 10-K may adversely affect Ensysce. Ensysce will not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

References in this Annual Report on Form 10-K to "we," "our," "us," the "Company" or "Ensysce" generally refer to Ensysce and its consolidated subsidiaries.

PART I

Item 1. Business

Corporate Information

We were originally incorporated in the State of Delaware in April 2003 as PharmacoFore, Inc. and, in January 2012, we changed our name from PharmacoFore, Inc. to Signature Therapeutics Inc. ("*Signature*"). On December 28, 2015, Signature, Signature Acquisition Corp., a wholly-owned subsidiary of Signature ("*SAQ*"), and Ensysce Biosciences, Inc. ("*EB*") entered into an Agreement and Plan of Merger ("*EB-ST Agreement*"). Pursuant to the EB-ST Agreement, SAQ merged with and into EB with EB surviving the merger as a wholly-owned subsidiary of Signature. As part of the transaction, Signature changed its name to "Ensysce Biosciences, Inc." ("*Former Ensysce*") and changed EB's name to EBI Operating Inc. On January 31, 2021, LACQ, Former Ensysce, and Merger Sub entered into the Merger Agreement. On June 30, 2021, pursuant to the Merger Agreement, Merger Sub merged with and into Former Ensysce, with Former Ensysce surviving the transaction as a wholly-owned subsidiary of LACQ. As part of the transaction, LACQ changed its name to "Ensysce Biosciences, Inc." and Former Ensysce changed its name to EBI OpCo, Inc. (the "*Merger*").

The mailing address of our principal executive office is 7946 Ivanhoe Avenue, Suite 201, La Jolla, California 92037. Our corporate telephone number is (858) 263-4196. Our website address is www.ensysce.com. Information contained on our website, or connected thereto, does not constitute part of, and is not incorporated by reference into, this Annual Report on Form 10-K.

Channels for Disclosure of Information

Investors, the media, and others should note that we announce material information to the public through filings with the SEC, the investor relations page on our website, blog posts on our website, press releases, public conference calls, webcasts, and our twitter feed (@EnsysceBio).

The information disclosed by the foregoing channels could be deemed to be material information. As such, we encourage investors, the media, and others to follow the channels listed above and to review the information disclosed through such channels.

Any updates to the list of disclosure channels through which we will announce information will be posted on the investor relations page on our website.

Business Overview

We are a clinical stage pharmaceutical company seeking to develop innovative solutions for severe pain relief while reducing the fear of and the potential for misuse, abuse, and overdose. We have also incorporated a 79.2%-owned subsidiary, Covistat, a clinical stage pharmaceutical company that is developing a compound utilized in our overdose protection program for the treatment of COVID-19 and cystic fibrosis. Certain of our affiliates own the remaining portions of Covistat. See "*Certain Relationships and Related Person Transactions*" for additional information.

We are currently developing product candidates designed to improve the safety and performance of prescription drugs. Our primary focus has been on opioid pain products and opioid use disorder products. Prescription opioid abuse and addiction present major burdens to society, resulting in significant costs, illnesses, and deaths, many of which we believe could be prevented through the use of our proprietary technologies. We believe the intertwined issues of (1) the widespread abuse of prescription opioids and (2) the resultant reluctance of many prescribers to write prescriptions for opioid analgesics, have resulted in the persistent under-treatment of patients with moderate-to-severe pain. Our platforms utilize a novel molecular delivery technology designed to deter prescription opioid abuse at the molecular level.

Our current development pipeline includes two new drug platforms - an abuse-resistant opioid prodrug technology – theTrypsin Activated Abuse Protection, or the TAAP platform, and an over-dose protection opioid prodrug technology - the Multi-Pill Abuse Resistant, or the MPAR™ platform. The TAAP platform is designed to seek to improve the care of patients with moderate to severe acute or chronic pain while reducing the human and economic costs associated with prescription opioid drug abuse. Our development pipeline of TAAP prodrugs is summarized in the table below. The MPAR™ platform when combined with our TAAP prodrugs is designed not only to seek to prevent abuse of prescription drugs but also to reduce overdose occurrences. Each prodrug is intended to be able to be combined with our MPAR™ technology for overdose protection. Additionally, nafamostat di-mesylate ("*nafamostat*"), which is an ingredient in our overdose protection combination products, is also being developed for the intended purpose of treating infection and pulmonary lung diseases.

The technology under the TAAP platform when applied to opioid drugs is designed to release clinically effective opioid drugs only when exposed to specific physiological conditions (i.e., when the drug is ingested and exposed to the digestive enzyme trypsin). Our lead product candidate, PF614, is a TAAP oxycodone prodrug that is a biologically inactive compound which can be metabolized in the body to produce a drug with demonstrable features aimed at resisting both oral and non-oral modes of prescription drug abuse. This approach differs from current formulation-based strategies such as OxyContin OP which uses Intac® Technology (crush-resistant polymers) and Extampza®ER which uses DETERx™ (insoluble fatty acid salts in polymers), in a number of ways.

First, the TAAP technology seeks to remove the ability of a user to abuse PF614 intravenously or intra-nasally. This is based on preclinical studies that show PF614 does not readily convert into oxycodone in the blood stream and trypsin is not present in the nasal passage. Accordingly, PF614 would not convert to oxycodone in the nose. Furthermore, the chemically modified and abuse-resistance TAAP opioid drug is unaffected by simple physical manipulations designed to extract abusable amounts of opioid, such as through kitchen chemistry.

Our portfolio of TAAP product candidates is based on a differentiated understanding of chemical reactivity and metabolism, as well as the key pillars of our unique approach which focuses on: (1) enzyme mediated metabolic activation localized in the gastrointestinal tract; (2) rearrangement chemistry to achieve ideal pharmacokinetic release of active drug products; and (3) robust packages of preclinical data that set forth the metabolic and chemical activation profile for each of our clinical candidates. This approach led to the filing of an Investigational New Drug application, or IND (116794), and a Phase 1 clinical trial for PF614, which was completed in February 2018. In addition, the clinical data from the Phase 1 trial demonstrated that oxycodone is released from PF614 as chemically designed, and that it was absorbed following oral administration of the TAAP PF614, given blood levels that matched the same release profile as the extended release oxycodone product, OxyContin OP.

The MPAR™ technology is a combination of TAAP prodrug and trypsin inhibitor nafamostat. It is designed to provide overdose protection to all TAAP prodrugs. MPAR™ applied to TAAP opioids enables the release of active opioid following ingestion of multiple doses, whether inadvertent or intentional. Nafamostat is a small molecule, highly potent protease inhibitor (trypsin inhibitor) with a steep dose response curve. MPAR™ at prescribed doses is designed to release of the active pharmaceutical ingredient. However, if the TAAP prodrug nafamostat combination (MPAR™) is taken in larger quantities than intended, the excess nafamostat is present to inhibit trypsin, thereby preventing metabolic activation of TAAP and averting a drug overdose. We believe the potential benefits to society of an opioid that resists both oral and parenteral abuse are considerable.

Our pipeline, developed over the course of 15 years of research and investment, includes three clinical-stage product candidates. While our principal focus and lead product candidates are geared towards combating abuse and overdose of opioid drugs, we have, over the years of research and development, discovered and recognized qualities and unique features of certain product candidates that may be useful in addressing other treatments. For example, we discovered the ability of nafamostat in inhibiting the action of enzymes associated with the COVID-19 infection, and, as such, have devoted efforts to develop an oral and inhalation drug product of nafamostat, for use against coronaviral infections and other pulmonary diseases such as cystic fibrosis.

PF614

PF614 is our lead TAAP prodrug candidate under development for the treatment of acute or chronic pain. PF614 is a delayed release TAAP prodrug designed to release oxycodone under certain specific physiological circumstances when taken orally. PF164 was evaluated for safety and pharmacokinetic release of oxycodone in a Phase 1 single ascending dose clinical trial in 64 healthy subjects. The trial showed that PF614 was well tolerated with no serious adverse events. The study also showed pharmacokinetics had a maximum blood concentration of oxycodone at 4 to 6 hours after swallowing PF614, demonstrating its delayed release profile. A second Phase 1b study was initiated in 2021 to evaluate PF614 delivered to healthy subjects twice daily for 4.5 days. This study evaluated both safety and PK, with a second part to evaluate the bioequivalence of PF614 versus OxyContin. Final data from this trial will be available in the second quarter of 2022.We believe PF614 has the potential to provide a safer alternative to the abuse deterrent formulated opioid products that are currently commercially available.

PF614-MPAR™

PF614-MPAR™, a combination product of PF614 and nafamostat has been designed to limit abuse potential by providing resistance to use through injection or inhalation and to provide overdose protection against excessive oral ingestion. Our IND application (150966) for PF614-MPAR™ received FDA allowance and we initiated a Phase 1 clinical trial to evaluate safety and PK in healthy subjects in December 2021. Data from this trial will be available in the second half of 2022.

Nafamostat

Nafamostat is an enzyme inhibitor (protease inhibitor) used in our combination overdose protection technology, MPAR™. Due to its ability to inhibit the action of enzymes associated with the COVID-19 infection, we are also developing an oral and inhalation drug product for use against coronaviral infections and other pulmonary diseases such as cystic fibrosis. An IND was submitted (149877) for the evaluation of oral nafamostat in coronaviral infections. A Phase 1 trial to evaluate safety and PK was completed in 2021.

Next Steps

We intend to undertake additional clinical studies in 2022. Two human abuse liability studies of PF614 will be initiated in the second and third quarter of 2022 to understand the tendency for drug abusers to like the effects achieved from taking PF614 either orally or nasally as compared to that of a comparator product such as crushed OxyContin. We are also exploring pain indications to evaluate PF614 for efficacy and safety which we are seeking to initiate by end of 2022. We are also planning to evaluate nafamostat in COVID-19 subjects when delivered as an oral drug product. The ability to undertake these studies will depend on additional financing. We have funded our operations to date primarily with proceeds from the sale of equity and borrowings under convertible promissory notes and federal grants. See "Convertible Promissory Notes" and "*Government Grants*" for additional information.

Our Strategy

We seek to become a leading specialty pharmaceutical company focused on addressing the safe use of pharmaceuticals by developing a broad portfolio of TAAP and MPAR™ products with enhanced safety features and benefits. Specifically, we intend to:

- *Capitalize on our management team's collective experience and expertise in the development and approval process of innovative drug delivery technologies that address medication safety*. We have received fast track designation for PF614, our lead drug candidate, from the FDA. However, fast track designation does not guaranty a faster development or regulatory review or approval process and does not assure FDA approval. We are currently devoting our efforts to develop PF614 for the severe pain market with acute and chronic pain indications, while bringing other TAAP and MPAR™ products through regulatory approval with the expertise of team members who have launched a number of products in the central nervous system, or CNS, space.

- *Leverage our proprietary technologies to develop a full line of pharmaceutical products.* Medication abuse and misuse is not limited to single drugs but often pervades entire drug categories. We have initiated programs to apply our TAAP and MPAR™ technology to other categories of prescription drugs such as amphetamine and methadone.

- *Commercialize our products through focus on the United States market to commercialize our lead products while licensing our technology internationally and through patent life extension*. We intend to bring PF614 and PF614-MPAR™ through regulatory approval to commercialization in the United States. We expect to seek licensing partners in jurisdictions outside the United States for our product candidates. We also expect to seek partners who wish to license our TAAP and MPAR™ technologies for patent life extension of their portfolio products, or to improve delivery or pharmacokinetic properties of certain of their drug candidates.

- *Maintain an efficient internal cost structure*. Our internal cost structure has been designed to enable us to focus on our lead drug products, PF614, PF614-MPAR™, and nafamostat oral and inhalation drug products clinically through to commercialization. We outsource many high-cost elements of development such as clinical trials. Outsourcing these functions minimizes our fixed overhead without reliance or dependence on individual third parties, and capital investment and thereby reduce our business risk in our view.

Our Strengths

We seek to achieve our strategic goals through the utilization of our key competitive strengths, including:

- *Our worldwide patent portfolio has extensive coverage in major markets and coverage in select secondary markets. These patents provide protection to the underlying molecules of both our immediate and extended-release drug candidates. We expect our patent portfolio will continue to expand and deepen as new products are developed and new markets are identified.* Our lead product candidates are new chemical entities and not simply re-formulations. Our TAAP prodrugs have a unique technology that has been demonstrated in our Phase 1 clinical trials for PF614.

- *Pedigree of our leadership team in all stages of discovery, development, marketing, and business development.* Our team has successfully developed and launched many successful products with multi-billion dollar selling market leaders in the CNS area.

- *Fast track designation*. Our lead clinical candidate, PF614, has received fast track designation from the FDA.

- *Received Federal grants from Federal agencies including NIDA, NIH.* We have received two large Federal government grants to support our MPAR™ overdose protection program and our opioid use disorder program from NIH/NIDA.

- *Clinical proof of concept.* We have conducted a Phase 1 trial with TAAP prodrug PF614. The trial demonstrated that, after oral administration of the TAAP prodrug, the corresponding opioid was measured in the subjects' blood.

Market Opportunity

Drug Abuse and Drug Overdose

Opioid pain medications are essential for improving the care and outcomes of a majority of Americans who live with chronic pain. A recent NIH study reported that 25.3 million adults suffered from pain every day for the preceding three months and almost 40 million adults experience severe levels of pain, which is linked to worse health status. Prescription opioids drugs, such as morphine, hydromorphone, hydrocodone, and oxycodone, have a long history of use for the management of patient pain. Prescriptions for opioid medications in 2020 totaled 153 million, with $4.2 billion in market size in the United States, where 80% of world's opioids are consumed.

The CDC recently provided recommendations for clinicians who provide pain care, defining acute pain (duration less than 1 month), subacute pain (duration of 1–3 months), or chronic pain (duration of 3 months or more), not including sickle cell disease related pain management, cancer pain treatment, palliative care, and end-of life care. These guidelines provide the market indications, acute and chronic, that Ensysce will explore for its TAAP and MPAR™ opioid products including PF614.

Opioids are offered in a variety of dosages including immediate-release tablets (or capsules), extended-release tablets (or capsules), patches, and other dose forms. Oxycodone is one of the most effective pain killers available today. This drug helps the patient to overcome pain and focus on his or her work. Opioids have an increased risk of dependence and, when used improperly, a common side effect of high doses of opioids like oxycodone can be euphoria, or a "high." As a result of these side effects, opioids have become amongst the most misused or abused prescription drugs in the United States. Opioid abuse was declared a public-health emergency in 2017 when more than 130 people died each day from opioid-related overdoses. Currently, that number has risen to over 200 deaths per day.

The large increase in overall overdose deaths is now driven by use of synthetic opioids, in particular fentanyl, as prescription opioids have become harder to obtain. From 2017 to 2018 the prescription opioid-involved death rates decreased by 13.5% showing that attention to the problem had beneficial effect. However, 1.6 million people reported having opioid use disorder ("Opioid Use Disorder") in 2019. Based on information from the CDC, the most common drugs involved in prescription opioid overdose deaths include Methadone, Oxycodone (such as OxyContin®), and Hydrocodone (such as Vicodin®). The CDC indicates that improving opioid prescribing, treatment of opioid use disorder, and prevention of opioid use disorder would help to improve the opioid crisis. Misuse or abuse of opioids is often done in one of the following manners:

- *Oral Excessive Tablet Abuse*. Generally recognized as the most prevalent route of administration by abusers, an abuser orally ingests more tablets (or capsules) than is recommended for pain relief.
- *Nasal snorting*. Crushed tablets are inhaled for absorption of the drug through the nasal tissues.

- *Injection.* The opioid is physically or chemically removed from the dosage and injected into the vein using a syringe.
- *Oral Manipulated Tablet Abuse*. Extended-release tablets or patches are crushed, chewed, or otherwise physically or chemically manipulated to defeat an extended-release mechanism and provide an immediate-release of the opioid for oral ingestion.
- *Poly-pharmacy*. Opioids are sometimes used in conjunction with alcohol, methamphetamine, or other drugs to accentuate the euphoria.
- *Overdose*. Users may accidentally introduce excessive quantities of drugs in their systems or combine drugs that may heighten the chance of adverse effects of drugs. Some patients may over-ingest drugs accidentally or with the express intent of suicide.
- *Chronic or prolonged use.* Chronic or prolonged use of opioids resulting in dependence is another form of misuse or abuse.

Amphetamines like Adderall are manufactured in pill form and are intended for oral ingestion. Fifty-three percent of Adderall prescriptions are prescribed to the 10.5 million adults that are diagnosed with attention deficit hyperactivity disorder, or ADHD. ADHD is the most common neurodevelopment disorder in children. Five million adults misuse stimulant medication annually, by using alternative consumption methods to achieve a more intense high faster; snorting or injecting are most-common methods of abuse. Both of these methods involve crushing pills.

We believe that having prescription drug products available that have a reduced potential for abuse by crushing and injecting, snorting, and chewing could provide an even greater reduction of prescription opioid related deaths in the abuse of opioids or amphetamines.

Nafamostat

Nafamostat's market opportunity is multifaceted. The oral form could be used alone or in combination with other antiviral drugs that target separate processes needed for virus product, such as RNA replication or viral protein processing. An inhaled form of nafamostat could be applied to patients that have a more severe stage of the disease.

Our lead clinical program is an oral drug product of nafamostat for use against COVID-19 and other coronaviral infections. The dosing and positioning of oral nafamostat will be similar to antiviral drug oseltamivir phosphate, Tamiflu®. Tamiflu® is a seasonal influenza treatment that is taken in oral form within two days of influenza symptoms starting and applying a two-dosage daily schedule. During the H5N1 outbreaks and the H1N1 and other coronavirus outbreaks, Tamiflu® had annual U.S. sales above $1 billion and has had cumulative sales of $15.9 billion since its launch in 1999.

The World Health Organization estimates influenza epidemics result in approximately three to five million cases of severe illness and 250,000 to 500,000 deaths each year. Nafamostat will be well positioned to generate revenue from several changing market conditions:

- As new virus strains of influenza and coronavirus create new outbreaks, there is a window of opportunity to grow or boost sales before production of the appropriate vaccine is increased.
- Applying our antiviral in situations of waning immunity to vaccines, particularly in the elderly, and in immunocompromised patients; seasonal influenza vaccines are approximately 45% effective since the 2010 influenza season.
- Universal influenza and coronavirus vaccines remain several years from market launch, making nafamostat a potential first line of defense against infections.
- There are only four antiviral treatments for early symptoms of influenza for hospitalized patients that have severe, complicated, or progressive illness, or who are at high risk for complications.

- The reality of unexpected and rapidly spreading influenza or coronavirus outbreaks causes healthcare systems to stockpile and replenish first response antivirals.
- Utilizing a drug repurposing model and the Hatch Waxman Act, we believe that we will be able to receive eight to ten years of market exclusivity in North America, European Union, and Japan. See "*—Intellectual Property*" for further detail.

Our Technology Platform Solution

TAAP Prescription Drugs

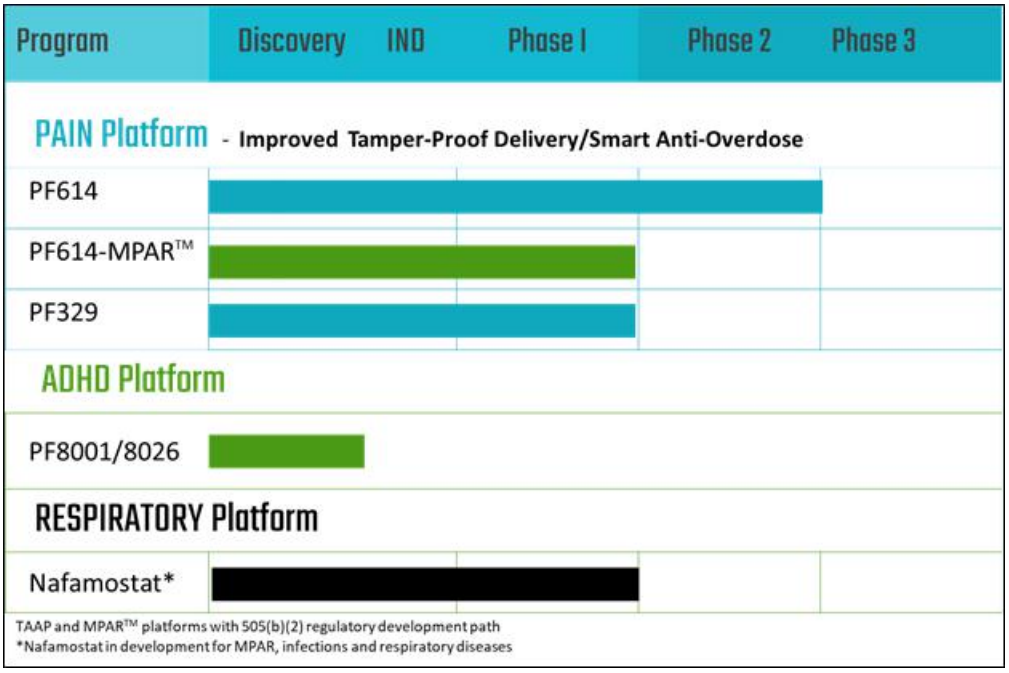
The technology under the TAAP platform utilizes a novel technology designed to deter prescription drug abuse at the molecular level. The molecular delivery system is designed to release clinically effective drugs only when exposed to specific physiological conditions (i.e., when the drug isingested and exposed to the digestive enzyme trypsin). We believe that our TAAP prodrugs delivery system demonstrates several features aimed at resisting both oral and non-oral modes of abuse. This platform's approach differs from current formulation-based strategies (abuse deterrent formulations, or ADFs) in a number of ways including that it is designed to be unaffected by simple physical manipulations (e.g. crushing and extraction and/or chewing of the dose form provided to patients). We believe the potential benefits to society of applying TAAP to opioids and amphetamines providing medication that resists both oral and parenteral abuse are considerable.

MPAR™ Prescription Drugs

MPAR™ combination therapy, involves co-formulating TAAP prodrugs with a trypsin inhibitor, nafamostat, which, when administered at prescribed dose levels, are intended to have no effect on the conversion of the prodrug to the active ingredient thus allowing normal drug plasma exposure levels. However, if the drug were taken in greater than prescribed quantities, the trypsin inhibitor would also be present at higher levels, inhibiting the first step in the activation process, preventing the conversion of the prodrug to the active ingredient thus limiting the potential to an overdose from the medication.

Our Development Programs

We are currently developing product candidates designed to improve the safety and performance of prescription drugs. Our primary focus has been on opioid pain products and opioid use disorder products. Our development pipeline of TAAP prodrugs is summarized in the table below. Each prodrug is intended to be able to be combined with our MPAR™ technology for overdose protection. Additionally, nafamostat, which is an ingredient in our overdose protection combination products, is also being developed for infection and pulmonary lung diseases. Besides our clinical candidates, we have a product portfolio of other TAAP and MPAR™ opioids that could potentially be developed to build on this pipeline.



Clinical agents

PF614

PF614 is a chemically modified, delayed onset oxycodone-derivative which releases clinically effective oxycodone only when exposed trypsin in the gut (i.e., when the drug is ingested). This approach differs from formulation-based strategies which are currently commercially available, in several ways. Foremost, the abuse-resistance provided by PF614 is designed to be unaffected by simple physical manipulations (e.g., extraction, chewing, and/or crushing). It also limits the bioavailability of active medication following co-ingestion of multiple doses.

Following ingestion, the release of oxycodone from PF614 proceeds via a two-step process comprised of (1) trypsin activation in the small intestine and (2) a subsequent intramolecular cyclization release reaction. This reaction releases oxycodone with concomitant formation of a cyclic urea metabolite. The time-course of oxycodone release from PF614 is a function of the kinetics of (i) the trypsin hydrolysis and (ii) the cyclization-release reaction. In the Phase 1 study of PF614, the time to maximal blood concentration of oxycodone (T_{max}) was five to six hours for the release of oxycodone and this time cannot be modified by crushing, chewing, or physically manipulating the drug product. Oxycodone safety, metabolism, and pharmacokinetics have been well studied.

PF614-101 Phase 1 Clinical Trial

PF614 (IND 116796) has been evaluated in a Phase 1 clinical study for safety and pharmacokinetics of oxycodone release in 64 healthy subjects in seven different closing cohorts from November 2016 to January 2018. This study was conducted for us by PRA Health Sciences – Early Development Services Lenexa, Kansas, principal investigator, Daniel Dickerson, M.D., Ph.D. to evaluate the safety and pharmacokinetics of PF614, as well as the pharmacokinetics of oxycodone at doses sufficient to characterize the extent to which plasma oxycodone is produced and maintained following oral ingestion of PF614 and was compared to the oxycodone released from extended release oxycodone from OxyContin OP. Subjects were randomized to receive a single dose of PF614 (dose of 15, 25, 50, 100, and 200 mg with 6 subjects per dosing group) or OxyContin OP (dose of 10, 20, 50, and 80 mg with 2 subjects per dosing group). New subjects were recruited for each cohort. Cohort 1 compared subjects receiving PF614 and OxyContin OP with and without naltrexone blockade. Naltrexone is an opioid blocker to prevent opioids from attaching to the opioid receptors, preventing the effect of the opioid medication such as pain relief, feeling of euphoria or respiratory depression. The single ascending dose study also compared the release of oxycodone from PF614 under both fasted and fed

conditions at the highest does of PF614 evaluated, 200 mg. The pharmacokinetics of the prodrug fragments was also evaluated. In addition, this study instructed as to the "conversion efficiency" of the PF614 prodrug to oxycodone, with respect to OxyContin.

Pharmacokinetic Analyses

The shape of the plasma concentration versus time curve of oxycodone was similar following administration of OxyContin OP (oxycodone extended release) and PF614. The efficiency of conversion for PF614 to oxycodone was determined to be approximately 86%. A PF614 dose of 50 mg yields oxycodone exposure comparable to a 20.01 mg dose of OxyContin, indicating a potency ratio of 0.40. This data has allowed us to match doses of PF614 to those of commercially available OxyContin OP.

Safety

A total of 64 subjects were included in this study, of which 23 (35.9%) experienced 47 treatment-emergent adverse events, or TEAEs. The majority of TEAEs were either gastrointestinal disorders or nervous system disorders with no deaths, serious adverse events, or severe TEAEs. Additionally, there were no discontinuations due to study drug-related adverse events. Over half of TEAEs were study drug related, but they were mostly mild in severity. The three TEAEs that were moderate in severity were nephrolithiasis, or kidney stones, nausea, and vomiting, with the nausea and vomiting being study drug related. Comparing safety data across cohorts, the data indicated that dose, naltrexone, and fed/fasted state had no clinically relevant effect on the safety profile of PF614. PF614 was generally well tolerated at doses up to 200 mg in healthy subjects.

Next Steps

We initiated additional clinical studies with PF614 in the fourth quarter of 2021. A multi ascending dose study with a bioequivalence arm, PF614-102 concluded enrollment, with data anticipated in the second quarter of 2022. In 2022, two human abuse liability studies will be initiated to understand the tendency for drug abusers to like the effects achieved from taking PF614 either orally or nasally as compared to that of a comparator product such as crushed OxyContin.

PF614-MPAR™

Our IND application (IND 150966) received FDA allowance and a Phase 1 study was initiated in December 2021 with first patients dosed. The study to evaluate PF614-MPAR™ is entitled "A Single Dose, 2 Part Study to Evaluate the Pharmacokinetics of Oxycodone, PF614, PFR06082, and nafamostat, when PF614 Solution is Co-Administered with nafamostat, as an Immediate Release Solution and/or Extended Release (ER) Capsule Formulations in Healthy Subjects".

PF614-MPAR™-101 Phase 1 Clinical Trial

The primary objectives of the Phase 1 study are to assess the pharmacokinetics of oxycodone, when PF614 solution is administered alone and with nafamostat as an immediate release solution and/or extended-release capsule prototypes. The study is designed to aid in the selection of the optimal nafamostat formulation and dose to combine with PF614 in order to provide oxycodone when a prescribed dose is taken yet attenuate the maximum plasma concentration (C_{max}) and the area under the concentration time curve (AUC) of oxycodone when more than the prescribed PF614-MPAR™ dose is taken. Extended-release prototype capsule formulations will be selected from a two-dimensional design space describing formulation variables for release rate and dose.

NAFAMOSTAT

NAF-101 Phase 1 Clinical Trial

We believe nafamostat has the potential to be effective in the treatment of patients with COVID-19 as it is an inhibitor of transmembrane protease Serine 2 (TMPRSS2) the protease responsible for cleaving the spike protein of SARS-CoV-2. While patients with COVID-19 typically present with fever and a respiratory illness, some patients also report gastrointestinal symptoms, such as diarrhea, vomiting, and abdominal pain. Studies have identified a recent strain of COVID-19 virus, SARS-CoV-2 RNA, in stool specimens of infected patients, and its viral receptor angiotensin converting enzyme 2 was found to be highly expressed in gastrointestinal epithelial cells. These suggest that SARS-CoV-2 can actively infect and replicate in the gastrointestinal tract, and oral nafamostat which acts locally in the gut may be able to reduce the ability of the virus to replicate. The purpose of our study was to evaluate the safety of oral nafamostat in healthy volunteers. This was a three-part single ascending dose study (Part 1) examining safety and pharmacokinetics of single doses of 50, 100, and 200 mg nafamostat administered sequentially on three separate days to a single cohort of eight subjects. The multiple ascending dose study (Part 2) administered 100 mg nafamostat twice daily to four healthy subjects and evaluated safety and pharmacokinetic for five days. A second cohort of four subjects received 200 mg nafamostat twice daily for five days and evaluated safety and pharmacokinetic. A final group of six healthy subjects received 200 mg nafamostat the multiple fixed dose study (Part 3) to evaluate the safety and tolerability of oral nafamostat solution administered three times daily.

Pharmacokinetic Analyses

Nafamostat was shown to have limited bioavailability at any dose level evaluated up to 200 mg.

Safety

There were no drug-related adverse events reported for nafamostat delivered at 200 mg three times daily, therefore additional dose levels are currently being examined for safety. We concluded that 200 mg can be delivered three times daily which may provide local effects in the gastrointestinal tract.

Next Steps

We are also planning to evaluate nafamostat in a Phase 2 clinical trial in COVID-19 subjects when delivered as an oral drug product.

Competition

Our industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. We expect to face competition from a number of sources, including pharmaceutical and biotechnology companies, generic drug companies, drug delivery companies, and academic and research institutions. Many of these existing and potential competitors have significantly greater financial resources, more people and other resources than we do.

The key competitive factors that are expected to affect the development and commercial success of our product candidates include their respective degree to limit human abuse potential, bioavailability, enhance therapeutic efficacy, and convenience of dosing and distribution. In addition, other factors include their respective safety, cost and tolerability profiles are likely to be important factors. Our lead product candidate, PF614, may also face competition from commercially available generic and branded immediate and extended-release opioid drugs other than oxycodone, including, but not limited to, fentanyl, hydromorphone, and oxymorphone, as well as opioids that may be currently in clinical development.

Obtaining an abuse-deterrent label through the FDA involves a lengthy and complicated process. We believe abuse-deterrent opioids represent a therapeutic option to maximize pain relief in patients for whom opioid analgesia is indicated, while reducing the risks of abuse and diversion. Before approval, the FDA evaluates the results from in vitro manipulation and extraction, pharmacokinetics, and clinical human abuse potential studies to determine whether the accumulated evidence is sufficient to warrant claims of abuse deterrence. Post-marketing studies may also be required to determine whether the marketing of a product with abuse-deterrent properties results in meaningful reductions in abuse, misuse, and related adverse clinical outcomes, including addiction, overdose, and death in the post-approval setting.

There are only four commercially available (in the United States) opioid drugs for chronic pain relief that have an abuse-deterrent label. These drugs are MorphaBond™ ER, marketed by Daiichi Sankyo, OxyContin® ER and Hysingla® ER, both of which are marketed by Purdue Pharma, LP, and Collegium Pharmaceutical, Inc.'s XTampza®ER. Hysingla® ER is a once-a-day hydrocodone extended-release product. Xtampza® ER is a twice daily, extended-release opioid formulation that contains microspheres that combine oxycodone with inactive ingredients to increase the difficulty of tampering. Xtampza®ER has abuse-deterrent properties in the FDA approved product label, and post-marketing data has shown Xtampza®ER abuse, misuse, and diversion and tampering are low relative to other prescription opioid analgesics.

Purdue Pharma LP is expected to have tighter marketing and management controls than it has exhibited in the past which may impact its overall market share. While Oxycontin OP is an abuse-deterrent formula that has impacted the ability to snort or inject, the drug has been documented to be abused through other means.

Several other companies including, but not limited to, Pfizer Inc., Daiichi Sankyo, Teva Pharmaceutical, Inc., Egalet Ltd., KemPharm Inc., Elysium Therapeutics Inc., and Acura Pharmaceutical, have either extended-release or abuse-deterrent products in various stages of development. Other companies offer products indicated for chronic, severe, long-term pain with various delivery technologies, but these products do not have abuse-deterrent claims on their labels.

We do not believe there are other companies developing products that have an overdose mechanism to compete with our MPAR™ technology.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for product candidates and any of our future product candidates, novel discoveries, product development technologies, and know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing or in-licensing United States and foreign patents and patent applications related to our proprietary technology, inventions, and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation, and potential in-licensing opportunities to develop and maintain our proprietary position.

Patents and Patent Applications

We own numerous patents and applications in the United States and significant commercial markets, such as Europe, China, and Japan, relating to our product candidates currently in development, as well as other product candidates that may be developed in the future. These patents, and patents that may issue from pending patent applications, are projected to expire between 2028 and 2041, subject to any patent term adjustment or extension that might be available in a particular jurisdiction. A table of the key patent families and their projected expiry dates is presented below.

	Jurisdiction of Filings	Earliest Projected Expiry Date
TAAP and MPAR™ Patents and Applications for Opioids		
Compositions Comprising Enzyme-Cleavable Ketone-Modified Opioid Prodrugs and Optional Inhibitors Thereof	U.S., Australia, Brazil, Canada, China, Europe*, Hong Kong, Israel, India, Japan, Mexico, Russia	2030
Compositions Comprising Enzyme-Cleavable Opioid Prodrugs and Inhibitors Thereof	U.S.	2030
Compositions Comprising Enzyme-Cleavable Oxycodone Prodrugs	U.S., Australia, Brazil, Canada, China, Europe*, Hong Kong, Israel, India, Japan, Russia	2032
Enzyme-Cleavable Methadone Prodrugs and Methods of Use Thereof	U.S.	2042
Compositions Comprising Enzyme-Cleavable Prodrugs and Controlled Release Nafamostat and Methods of Use Thereof	U.S.	2042
Active Agent Prodrugs with Heterocyclic Linkers	U.S., Australia, Brazil, Canada, China, Europe*, Hong Kong, Israel, India, Japan, Russia	2032
Nafamostat Patents and Applications		
Methods of Treating coronavirus infections and COVID-19	Patent Cooperation Treaty member countries	2041
Oral formulations of Nafamostat	U.S.	2042
Methods of Treating Respiratory Diseases with mucostasis	Germany, France, Italy, United Kingdom	2028
TAAP and MPAR™ Patents and Applications for Amphetamines		
Compositions Comprising Enzyme-Cleavable Amphetamine Prodrugs and Inhibitors Thereof	U.S., Europe*	2031
Compositions Comprising Enzyme-Cleavable Amphetamine Prodrugs and Inhibitors Thereof	U.S., Europe*	2040

*"Europe" refers to patent applications filed in, and patents issued by, the European Patent Office ("*EPO*"), which can provide the basis for rights in multiple countries that are members of the European Patent Convention.

While we seek broad coverage under our existing patent applications, there is always a risk that an alteration to the products or processes may provide sufficient basis for a competitor to avoid infringing our patent claims. In addition, patents, if granted, expire, and extension of term may not be available. We also cannot provide any assurance that any patents will be issued from our pending or any future applications or that any potentially issued patents will adequately protect our product candidates.

The enforceable term of an individual patent varies depending on the date of filing of the patent application, the date of patent issuance, and the statutory term of patents in the countries in which they are obtained. Generally, in the United States, patents are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a period due to delay by the United States Patent and Trademark Office ("*USPTO*") in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years, the total patent term including the restoration period must not exceed fourteen years following FDA approval, and the scope of patent coverage is limited to the scope of the FDA approved product. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective non-provisional filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent

would require us to alter our development or commercial strategies for our products or processes, or to obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future products may have an adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, please see "*Risk Factors—Risks Related to Our Intellectual Property.*"

TAAP and MPAR™ Patents and Applications for Opioids

Following our merger with Signature, we became the owner of patent families that include several granted U.S. patents, as well as granted patents and pending patent applications in numerous foreign jurisdictions, including Australia, Brazil, Canada, China, the EPO, India, Japan, and Russia, relating to chemically modified opioids, such as oxycodone, methadone, and hydromorphone, covalently linked using specific linkers to a gastrointestinal enzyme-cleavable moiety and pharmaceutical compositions containing these modified opioids, pharmaceutical compositions containing these modified opioids and a gastrointestinal enzyme inhibitor, and methods of using the same to treat pain. Three of these patent families are variously directed to ketone containing opioids and cover PF614 and PF614-MPAR™ and certain methadone TAAP product candidates that are still in the discovery phase. These three families contain issued patents in the United States and certain foreign jurisdictions, including Australia, Brazil, Canada, China, the EPO, India, Japan, and Russia and expire between 2030 and 2032, subject to any applicable patent term extension that might be available in a jurisdiction. We also own a patent family with pending applications filed in the U.S., Taiwan and under the Patent Cooperation Treaty, which applications include coverage for oral formulations of PF614-MPAR™, which if pursued and issued would expire in 2042, subject to any potential patent term adjustment or extension that may be available in a jurisdiction. We also own one patent family that includes granted patents in the United States, as well as granted patents and pending patent applications in numerous foreign jurisdictions, including Australia, Brazil, Canada, China, the EPO, India, Japan, and Russia, relating to chemically modified ketone-containing agents, such as oxycodone, methadone, and hydromorphone, covalently linked using specific linkers to a gastrointestinal enzyme-cleavable moiety, pharmaceutical compositions containing these modified ketone-containing agents, pharmaceutical compositions containing these modified ketone-containing agents and a gastrointestinal enzyme inhibitor, and methods of using the same to treat pain, would cover certain methadone TAAP product candidates that are still in discovery phase and have an earliest expiration date in 2030. While we own these patent families, we have not updated records in the various patent offices to reflect our ownership of these patent families. Failure to update such ownership may result in an innocent purchaser potentially acquiring rights in such patents that are adverse to our interests. Furthermore, as noted above, we have not obtained assignments for certain patent applications relating to abuse-resistant amphetamines.

We believe that one patent covering PF614 will be eligible for up to five years of patent term extension in the United States and intend to pursue such extension. In addition to patent exclusivity until at least 2032, under the provisions of the Hatch-Waxman Act, upon any approval in the United States, we believe that PF614 will be eligible for five-year New Chemical Entity, or NCE, regulatory exclusivity, during which time no 505(b)(2) New Drug Application, or NDA, or Abbreviated New Drug Application, or ANDA, can be approved that contains the same active moiety as the chemical entity in the PF614 NDA. In addition, if an ANDA or 505(b)(2) applicant were to file its application referencing the NDA for PF614 before expiration of our formulation patent and the applicant asserted that the patent is invalid or would not be infringed, it may be subject to additional waiting periods prior to the FDA's approval (including a statutory thirty-month stay, starting at the end of the five-year NCE regulatory exclusivity period, if we sue for infringement, or a shorter period if the patent expires of there are certain settlements or judicial decisions in the patent litigation) and may ultimately be required to wait until the natural expiration of our compositions patents if the patents are found to be valid and infringed by the challenging applicant. For more information please see "*—Patents and Patent Applications."*

Nafamostat Patents Applications

We own one pending Patent Cooperation Treaty, or PCT, application directed to the use of orally administered nafamostat for the treatment of infections caused by coronaviruses, including COVID-19, and a pending PCT, U.S. and Taiwan application directed to oral formulations of nafamostat. We intend to pursue these applications in the United States and other significant commercial markets and any patents that may be issued would expire in 2041 and 2042, respectively, subject to any applicable patent term adjustment or extension in a particular jurisdiction. Additionally, we acquired one European patent from Mucokinetica that is directed to the use of certain compounds, including nafamostat, for the manufacture of a medicament for the treatment of respiratory diseases with mucostasis or poor mucus clearance. This patent was validated in Germany, France, Italy, and the United Kingdom and expires in 2028, subject to any applicable patent term extension that might be available in Europe Union or United Kingdom. While we own this patent family, we have not updated the records in the various patent offices to reflect our ownership of this patent family. Failure to update such ownership may result in an innocent purchaser potentially acquiring rights in such patents that are adverse to our interests. Currently, we do not have any issued patent or pending application directed to methods of treating infections caused by coronaviruses, including COVID-19, with inhaled nafamostat. In addition to patent exclusivity, under the provisions of the Hatch-Waxman Act, upon any approval in the United States, we believe that nafamostat will be eligible for five-year NCE regulatory exclusivity, during which time no 505(b)(2) NDA or ANDA can be approved that contains the same active moiety as the chemical entity in the nafamostat NDA. In addition, if an ANDA or 505(b)(2) applicant were to file its application referencing the NDA for nafamostat before expiration of our use patent and the applicant asserted that the patent is invalid or would not be infringed, it may be subject to additional waiting periods prior to the FDA's approval (including a statutory thirty-month stay, starting at the end of the five-year NCE regulatory exclusivity period, if we sue for infringement, or a shorter period if the patent expires of there are certain settlements or judicial decisions in the patent litigation) and may ultimately be required to wait until the natural expiration of our compositions patents if the patents are found to be valid and infringed by the challenging applicant. For more information, please see "*—Patent and Patent Applications*."

TAAP and MPAR™ Patents and Applications for Amphetamines

Following the merger with Signature, we became the owner of one patent family that includes issued patents in the United States and numerous European foreign jurisdictions (through the EPO), and a pending application in the United States, relating to chemically modified amphetamines covalently linked to a gastrointestinal enzyme-cleavable moiety, pharmaceutical compositions containing the modified amphetamines, pharmaceutical compositions containing the modified amphetamines and a gastrointestinal enzyme inhibitor and methods of using the same to treat a subject. While we own this patent family, we have not updated the records in the various patent offices to reflect our ownership of this patent family. Failure to update such ownership may result in an innocent purchaser potentially acquiring rights in such patents that are adverse to our interests. In addition, we own one patent family with pending applications in the United States and the EPO directed to pharmaceutical compositions containing chemically modified amphetamines covalently linked to a gastrointestinal enzyme-cleavable moiety and a trypsin inhibitor and methods of using the same to treat a subject. We have not obtained assignments from all of the inventors of this patent family to date, which could negatively impact our ability to pursue or enforce this application. If issued, these patent applications would expire between 2031 and 2040, subject to any applicable patent term adjustment or extension that might be available in a jurisdiction.

Trademarks and Trade Secrets

We intend to pursue trademark registrations in the United States and other significant commercial markets for our product candidates as they progress through clinical development.

Furthermore, we rely upon trade secrets, know-how, continuing technological innovation, and potential in-licensing opportunities to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality and invention assignment agreements with our commercial partners, collaborators, employees, and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with an employee or a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-

how and inventions.

Manufacturing and Supply

Our drug substance and drug products are manufactured by contract manufacturing organizations. We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. See "*Risk Factors*" for more information. Although we intend to rely on third-party contract manufacturers to produce our product candidates, we have personnel with experience managing the third-party contract manufacturers who are expected to produce our product candidates and other product candidates or products that we may develop in the future.

Our lead product candidate, PF614, is small molecule opioid prodrug. As such, it is a controlled substance, regulated by the Drug Enforcement Administration ("*DEA*") and state-controlled substance authorities. Our third-party manufacturers will be required to be registered with DEA and will be responsible for obtaining adequate quota to manufacture and otherwise handle controlled substances.

We currently engage third parties to provide clinical supplies of PF614 and nafamostat. We also currently engage a third-party manufacturer to provide drug product manufacture of PF614, PF614-MPAR™, and nafamostat. We currently have sufficient supplies of PF614 and nafamostat on hand for our current clinical trial needs. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability, and quality. See "*Risk Factors*" for more information.

Recro Manufacturing Agreement

Pursuant to the Recro Agreement, we engaged Recro to manufacture PF614 and other clinical trial materials under cGMP conditions and provide stability studies with respect to our PF614 clinical trials. Pursuant to the agreement, Recro will create placebo capsules, PF614 powder-filled capsules and provide us with master batch records and a GMP manufacturing report upon completion of manufacturing and analytical activities. Under the Recro Agreement, Recro also generated stability data according to ICH program for two formulations to provide stability data for shelf-life assessment with respect to our Phase II clinical trial. We have agreed to pay Recro $173,000 and pass-through costs, estimated at $14,000 at the time of the agreement, for the manufacturing and services provided under the Recro Agreement. The term of the Recro Agreement began on September 19, 2019 and continues until the completion of the manufacturing and services described in therein. However, we paused the Recro Agreement in early 2020 in connection with the timing of our PF614 clinical studies and resumed in the first quarter of 2021. We expect to enter into additional related agreements with Recro. In the event that Recro is unable to perform the services promised under the Recro Agreement, we may be subject to unforeseen costs and delays with respect to our clinical trials and be unable to replace the Recro Agreement on terms as favorable to us. See "*Risk Factors—We expect to be completely dependent on third parties to manufacture our product candidates, and our commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to maintain a compliance status acceptable to the FDA or comparable foreign regulatory authorities, fail to provide to us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices*" for more information.

Government Grants

We received funding under federal grant award programs funded by governmental agencies, such as the NIH and NIDA. Specifically, for fiscal year 2021, we received funding revenue of approximately $3.5 million in federal grants, approximately $2.6 million from the NIH related to the Phase 1 clinical trial for PF614 MPAR™ and approximately $0.9 million from NIDA under our five-year award to undertake the preclinical development of our opioid use disorder- MPAR^{TM} technology. We may apply for additional grant funding from these or similar governmental agencies in the future. See "*Risks Related to Our Business, Financial Condition and Capital Requirements*" for additional information.

Convertible Promissory Notes

On September 24, 2021, we entered into a Securities Purchase Agreement (the "SPA") for an aggregate financing of $15.0 million with institutional investors. A first closing under the SPA occurred on September 24, 2021, and a second closing under the SPA occurred on November 5, 2021. At the first closing, we issued to the investors (i) senior secured convertible promissory notes in the aggregate principal amount of $5.3 million for an aggregate purchase price of $5.0 million and (ii) warrants to purchase 361,158 shares of the Company's common stock in the aggregate at an exercise price of $7.63 per share. At the second closing, the Company issued to the institutional investors referenced above, (i) senior secured convertible promissory notes in the aggregate principal amount of $10.6 million for an aggregate purchase price of $10 million and (ii) warrants to purchase 722,317 shares of the Company's common stock in the aggregate at an exercise price of $7.63 per share.

GEM Facility

Pursuant to the GEM Agreement, we are entitled to draw down up to $60.0 million of gross proceeds from GEM Global in exchange for shares of our common stock, subject to meeting the terms and conditions of the GEM Agreement. This share subscription facility is available for a period of 36 months from the closing date of the Merger. A draw down is subject to limitations on the amount that is drawn under the facility and must comply with certain conditions precedent including the listing of our shares on a principal market (which includes Nasdaq), having the necessary number of shares that are issuable pursuant to the draw down registered under an effective registration statement, and other notice and timing requirements. Upon our valid exercise of a draw down, pursuant to delivery of a notice and in accordance with other conditions, GEM Global is required to pay, in cash, a per-share amount equal to 90% of the average closing bid price of the shares of our common stock recorded by Nasdaq during the 30 consecutive trading days commencing on the first trading day that is designated on the draw down notice. In no event may our draw down requests exceed 400% ("*Draw Down Limit*") of the average daily trading volume for the 30 trading days immediately preceding the date we deliver the draw down notice. The SPA limits our ability to execute certain debt and equity financings, including our existing $60.0 million share subscription facility, while the 2021 Notes remain outstanding. See, "*Liquidity and Capital Resources*" for a detailed description of the GEM Facility.

Government Regulation

In the United States, pharmaceutical products are subject to extensive regulation by the FDA, and those pharmaceutical products that are controlled substance are also subject to extensive regulation by the DEA. The FDC Act, the CSA, and other federal, state, and local statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, prescribing, dispensing, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Pharmaceutical products used for the prevention, treatment, or cure of a disease or condition of a human being are subject to regulation under the FDC Act. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending NDAs, revocation of licensing authority, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

The FDA Drug Approval Process

FDA approval is required before any new drug can be marketed. A new drug is one not generally recognized, by experts qualified by scientific training and experience, as

safe and effective for its intended use. The process of drug development is complex and lengthy. The activities undertaken before a new pharmaceutical product may be marketed in the United States generally include, but are not limited to, preclinical studies; submission to the FDA of an IND, which must become active before human clinical trials may commence; adequate and well-controlled human clinical trials to establish the safety and efficacy of the product; submission to the FDA of an NDA; filing of the NDA by FDA; satisfactory completion of an FDA pre-approval inspection of the clinical trial sites and manufacturing facility or facilities at which both the active ingredients and finished drug product are produced to assess compliance with, among other things, patient informed consent requirements, the clinical trial protocols, current Good Clinical Practices, or GCP, and GMPs; and FDA review and approval of the NDA prior to any commercial sale and distribution of the product in the United States.

Preclinical studies include laboratory evaluation of product chemistry and formulation, and in some cases, animal studies and other studies to preliminarily assess the potential safety and efficacy of the product candidate. The results of preclinical studies together with manufacturing information, analytical data, and detailed information including protocols for proposed human clinical trials are then submitted to the FDA as a part of an IND. An IND must become effective, and approval must be obtained from an Institutional Review Board ("*IRB*") prior to the commencement of human clinical trials. The IND becomes effective 30 days following its receipt by the FDA unless the FDA objects to, or otherwise raises concerns or questions and imposes a clinical hold. We, the FDA, or the IRB may suspend or terminate a clinical trial at any time after it has commenced due to safety or efficacy concerns or for commercial reasons. In the event the FDA imposes a clinical hold, the IND sponsor must address any outstanding FDA concerns or questions to the satisfaction of the FDA before clinical trials can proceed or resume.

Human clinical trials are typically conducted in three sequential phases that may sometimes overlap or be combined:

In Phase 1, the initial introduction of the drug into patients, the product is tested to assess safety, dosage tolerance, metabolism, pharmacokinetics, pharmacological actions, side effects associated with drug exposure, and to obtain early evidence of a treatment effect if possible. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, determine optimal dose and regimen, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical effects and confirm efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the drug. In rare instances, a single Phase 3 trial may be sufficient when either (1) the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) the single trial is supported by other confirmatory evidence.

In addition, the manufacturer of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing and distribution of the product may begin in the United States. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $3.1 million. Under an approved NDA, the applicant is also subject to an annual program fee, currently approximately $370,000. These fees typically increase annually. Under limited circumstances, an applicant may be exempt from or seek a waiver of the application fee requirement.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the FDA's determination that it is adequately organized and sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals to complete the review of NDAs. For a standard review, the goal for review of a new molecular entity ("*NME*") is ten months from the date the FDA files the NDA, while the goal for review of a non-NME is ten months from the date of receipt of the NDA. For an NDA that has received a priority review designation from the FDA, the goal for review of an NME is six months from the date the FDA files the NDA, while the goal for review of a non-NME is six months from the date of receipt of the NDA. An NDA can receive a priority review designation when the FDA determines the drug has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority reviews may be extended by the FDA for three or more additional months to consider certain late-submitted information, or information intended to clarify information already provided in the NDA submission.

The FDA may also refer applications for novel drug products, as well as drug products that present difficult questions of safety or efficacy, to be reviewed by an advisory committee—typically a panel that includes clinicians, statisticians, and other experts—for review, evaluation, and a recommendation as to whether the NDA should be approved. The FDA is not bound by the recommendation of an advisory committee, but generally follows these recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug product is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory, and the NDA contains data that provide substantial evidence that the drug is safe and effective in the claimed indication.

After the FDA evaluates the NDA and completes any clinical and manufacturing site inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the NDA submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing and distribution of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("*REMS*") to help ensure that the benefits of the drug outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure a products safe use ("*ETASU*"). An ETASU REMS can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Changes to some of the conditions established in an approved NDA, including changes in indications, product labeling, manufacturing processes, or facilities, require submission and FDA approval of a new NDA, or supplement to an approved NDA, before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing original NDAs.

Section 505(b)(2) NDAs

An alternative to the NDA pathway described above is an NDA submitted under Section 505(b)(2) of the FDC Act, which enables the applicant to rely, in part, on the FDA's prior findings in approving a similar product or published literature in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for modified formulations, new routes of administration, or new uses of previously approved products. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on the FDA's prior findings of safety or effectiveness is scientifically appropriate, it may eliminate the need to

conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Fast Track Designation and Priority Review

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. Any product submitted to FDA for marketing, including under a fast-track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

The Hatch-Waxman Amendments

Under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, a portion of a product's U.S. patent term that was lost during clinical development and regulatory review by the FDA may be restored. The Hatch-Waxman Amendments also provide a process for listing patents pertaining to approved products in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the " *Orange Book*") and for a competitor seeking approval of an application that references a product with listed patents to make certifications pertaining to such patents. In addition, the Hatch-Waxman Amendments provide for a statutory protection, known as non-patent exclusivity, against the FDA's acceptance or approval of certain competitor applications.

Patent Term Extension

Patent Term Extension ("*PTE*") in the United States can compensate for lost patent grant time during product development and the regulatory review process for a patent that covers a new product or its use. This PTE period is generally one-half the time between the effective date of an IND (falling after issuance of the patent) and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application, provided the sponsor acted with diligence. PTEs that can be obtained are for up to five years beyond the expiration of the patent or fourteen years from the date of product approval, whichever is earlier. Only one patent applicable to an approved drug may be extended and the extension must be applied for prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a nonprovisional patent application related to the patent. A U.S. patent also may be accorded patent term adjustment, or PTA, under certain circumstances to compensate for delays in obtaining the patent from the USPTO. In some instances, such a PTA may result in a U.S. patent term extending beyond 20 years from the earliest date of filing a non-provisional patent application related to the U.S. patent. In addition, in the United States, the term of a U.S. patent that covers an FDA-approved drug may also be eligible for a patent term extension, or PTE, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a PTE of up to five years beyond the expiration of the patent. The length of the PTE is related to the length of time the drug is under regulatory review. PTE cannot extend the remaining term of a patent beyond a total of fourteen years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and certain other jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for PTEs on patents covering products eligible for PTE. We plan to seek PTEs for any of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

We also believe that (1) PF614 and nafamostat will be eligible for a five-year NCE regulatory exclusivity, and (2) PF614-MPAR™ will be eligible for a three-year clinical investigation, or CI, regulatory exclusivity, under the Hatch-Waxman Act, during which time no ANDA can be approved.

Under the Hatch-Waxman Act, patents covering the product such as patents claiming the approved composition of matter, approved methods of use, approved formulations, and approved dosing and administration shall be listed in the Orange Book, which identifies drug products approved by FDA under the FDC Act. Applicable regulatory exclusivities, such as the five-year NCE exclusivity and the three-year CI exclusivity, are also listed in the Orange Book. If an ANDA or 505(b)(2) applicant were to file its application before expiration of all patents listed in the Orange Book, it must certify whether it will either honor or challenge all the patents listed in the Orange Book. If an Orange Book listed patent is challenged and we sue the ANDA or 505(b)(2) applicant for infringement, a statutory 30-month stay of approval, started at the end of the NCE exclusivity period, will be put in place that will prohibit the FDA from finally approving the ANDA or 505(b)(2) application until the 30-months have expired or after a court has held in favor of the ANDA or 505(b)(2) applicant. The 30-month stay begins at the end of the five-year NCE exclusivity period. If the Orange Book listed patent(s) is ultimately held valid and infringed, the ANDA or 505(b)(2) applicant will not be finally approved until the Orange Book listed patent(s) expires. If a pediatric study is requested by the FDA in a Pediatric Written Request, or PWR, and we complete the pediatric study according to the terms of the PWR, all unexpired Orange Book listed exclusivities (patent or regulatory) will be extended by six months.

Similar provisions are available in Europe, Japan, and certain other jurisdictions to extend the exclusivity of a patent that covers an approved drug. In Europe, we believe PF614 and nafamostat will be eligible for 10 years of regulatory exclusivity from European Marketing Application, or EMA, approval. In Japan, we believe PF614 will be eligible for eight years of regulatory exclusivity from a Japanese new drug application, or J-NDA, approval.

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims covering the applicant's product or method of using the product. Upon approval of a drug, each of the patents identified in the application for the drug are then published in the FDA's Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active

ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a Section VIII statement certifying that its proposed ANDA labeling does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been filed with and accepted by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

An applicant submitting an NDA under Section 505(b)(2) of the FDC Act, which permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference, is required to certify to the FDA regarding any patents listed in the Orange Book for the approved product it references to the same extent that an ANDA applicant would.

Market Exclusivity

Market exclusivity provisions under the FDC Act also can delay the submission or the approval of certain applications. The FDC Act provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity ("*NCE*"). A drug is entitled to NCE exclusivity if it contains a drug substance with no active moiety of which has been previously approved by the FDA. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a Paragraph IV certification. For a drug that has been previously approved by the FDA, the FDC Act also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the new conditions of use and does not prohibit the FDA from approving ANDAs for drugs for the original conditions of use, such as the originally approved indication. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA. This regulation includes, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, who may or may not grant approval or may include in a lengthy review process.

Prescription drug advertising is subject to federal, state, and foreign regulations. In the United States, the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act ("*PDMA*"), a part of the FDC Act. In addition, Title II of the Federal Drug Quality and Security Act of 2013, known as the Drug Supply Chain Security Act or the DSCSA, has imposed new "track and trace" requirements on the distribution of prescription drug products by manufacturers, distributors, and other entities in the drug supply chain. These requirements are being phased in over a ten-year period. Unless the products were packaged prior to November 27, 2018, the DSCSA requires product identifiers (i.e., serialization) on prescription drug products in order to establish an electronic interoperable prescription product system to identify and trace certain prescription drugs distributed in the United States. The DSCSA replaced the prior drug "pedigree" requirements under the PDMA and preempts existing state drug pedigree laws and regulations. The DSCSA also establishes requirements for the licensing of wholesale distributors and third-party logistic providers. These licensing requirements preempt states from imposing licensing requirements that are inconsistent with, less stringent than, directly related to, or otherwise encompassed by standards established by FDA pursuant to the DSCSA. Until FDA promulgates regulations to address the DSCSA's new national licensing standard, current state licensing requirements typically remain in effect.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific facilities and in accordance with cGMP. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural, and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using contract manufacturers, laboratories, or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such product or may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market.

The CSA and DEA Regulation

Our products are regulated as "controlled substances" as defined under the CSA and regulations promulgated by DEA. The law and regulations establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, and other requirements administered by DEA.

Controlled substances are classified into five schedules: Schedule I, II, III, IV, or V, depending on the abuse potential. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV, or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

PF614 will be classified as a Schedule II controlled substance under the CSA and regulations because it contains oxycodone which is already regulated as a Schedule II controlled substance. Consequently, the manufacturing, shipping, storing, selling, prescribing, and dispensing of our products is subject to a high degree of regulation. Schedule II drugs are subject to the strictest requirements for registration, security, recordkeeping, and reporting. Facilities must maintain complete and accurate inventories and records of all controlled substances received, manufactured, stored, and distributed. These facilities must comply with strict security requirements to prevent diversion of drugs in their possession. Also, distribution and dispensing of these drugs are highly regulated. For example, all Schedule II drug prescriptions must be signed by a physician, presented to a pharmacist and, generally limited to a 30-day supply, and may not be refilled, that is, a new prescription is required.

Annual registration is required for any facility that manufactures, distributes, imports, or exports any controlled substance. Also, practitioners and pharmacies are required to register every three years. The registration is specific to the particular location, activity, and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances the facility is authorized to handle. Our contract manufacturers must be registered with DEA.

In addition, the CSA establishes an annual quota system that limits the manufacturing of API and dosage forms in the United States of Schedule I and II controlled substances. First, the DEA establishes an annual aggregate quota for how much active opioid ingredients, such as oxycodone and tapentadol, may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. The limited aggregate amount of opioids that the DEA allows to be produced in the United States each year is allocated among individual companies, which must submit applications annually to the DEA for individual production quotas. Also, dosage form manufacturers must also request a procurement quota to acquire opioid API to manufacture dosage forms for distribution. We and our contract manufacturers must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance, including oxycodone base for use in manufacturing PF614. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year. DEA has substantial discretion in whether or not to make such adjustments. Our contract manufacturers must apply for and obtain the necessary quotas on an annual basis.

In November 2017, the DEA reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the United States in calendar year 2018 by 20%. In October 2018, the SUPPORT Act was enacted, which included amendments to the CSA to require that appropriate quota reductions be made after estimating potential for diversion. DEA announced that the estimate is based on rates of overdose deaths and abuse, the overall public health impact related to specific controlled substances and may include other factors as appropriate. For 2019, the DEA proposed decreased manufacturing quotas for the six most frequently misused opioids, including oxycodone, by an average of 10% as compared to the 2018 quotas. In October 2019, consistent with the SUPPORT Act, DEA proposed additional regulations to amend the manner in which the agency grants quotas to manufacturers. The proposed regulations will establish use-specific quotas, including commercial sales, product development, transfer, replacement, and packaging. To decrease the risk of diversion and increase accountability, inventory allowances will be reduced, and procurement quota certifications will be required. The DEA proposed further decreasing manufacturing quotas in 2020 for five of the six opioids (fentanyl, hydrocodone, hydromorphone, oxycodone, and oxymorphone), by an average of 28%. For 2021, the DEA decreased the aggregate quota for oxycodone by about 13% and for hydrocodone by about 10% from the final established 2020 quotas. Because PF614 is regulated as a Schedule II controlled substance, it is subject to the DEA's aggregate, individual production, and procurement quota scheme.

Ordering and distribution of any Schedule I or II controlled substance are also subject to special ordering requirements under either the electronic Controlled Substance Ordering System ("*CSOS*") or use of DEA Form 222s. Information regarding specific transactions are reported to DEA, and cumulative reports of such transactions are required monthly/quarterly.

The DEA also requires drug manufacturers to design and implement a system that identifies and reports suspicious orders of controlled substances. Such orders include those of unusual size, those that deviate substantially from a normal pattern, and those of unusual frequency. Manufacturers must refuse to complete any sale and report to DEA any orders for which it is unable to resolve any potential "red flags." A compliant suspicious order monitoring system includes well-defined due diligence, "know your customer" process as well as systems to identify and monitor ordering and sales of controlled substances.

To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, especially security and recordkeeping and as manifested in loss or diversion or inability to account for all controlled substances, can result in administrative, civil, or criminal enforcement action that could have a material adverse effect on our business, results of operations, and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. The DEA may also reduce or deny quota to manufacturing facilities based on non-compliance with these requirements. In certain circumstances, violations could result in criminal proceedings.

Individual states also independently regulate controlled substances.

Legislative and Regulatory Initiatives for Opioids

In response to widespread prescription opioid abuse, the United States government and a number of state legislatures have enacted legislation and regulations intended to fight the opioid epidemic. The number and scope of legislative and regulatory actions, particularly in the last three years, emphasize the severity of the opioid epidemic and its impact on our society. The FDA has stated that addressing prescription drug abuse is a priority and has reaffirmed that the development of abuse-deterrent opioids is a key part of that strategy.

Recent actions to address the opioid abuse epidemic include:

- FDA guidance: In April 2015, the FDA adopted final guidance regarding studies and clinical trials that should be conducted to demonstrate that a given formulation has abuse-deterrent properties, how those studies and clinical trials will be evaluated, and what product labeling claims may be approved based on the results of those studies and clinical trials. The guidance describes four categories of abuse-deterrence studies and clinical trials: Categories 1, 2, and 3 consist of pre-marketing studies and clinical trials designed to evaluate a product candidate's potentially abuse-deterrent properties under controlled conditions, while Category 4, post-marketing clinical trials and studies, assesses the real-world impact of abuse-deterrent formulations. The final guidance also provides examples of product label claims that may be made based on the results of the corresponding studies and clinical trials.

- FDA Opioids Action Plan: In February 2016, the FDA released an action plan to address the opioid abuse epidemic and reassess the FDA's approach to opioid medications. The FDA's plan is part of a broader initiative led by the U.S. Department of Health and Human Services ("*HHS*"), to address opioid-related overdose, death, and dependence.

- CDC Prescribing Guidelines: In March 2016, the CDC released a new Guideline for Prescribing Opioids for Chronic Pain intended to assist primary care providers treating adults for chronic pain in outpatient settings. The guideline provides recommendations to improve communications between doctors and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy.

- Enhanced Warnings and Safety Labeling: In March 2016, the FDA announced required enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose, and death. Subsequently, there have been several class-wide labeling changes, including the addition of boxed warnings relating to serious risks of using certain opioids medications along with benzodiazepines and other central nervous system depressants, including alcohol (Decembers 2016); and additional information relating to the new class-wide REMS (Septembers 2018).

- Enactment of the Comprehensive Addiction and Recovery Act ("*CARA*"): In 2016, the CARA was enacted to address the national epidemics of prescription opioid abuse and heroin use. Consistent with the initiatives of HHS, this legislation sought to, among other things, expand the availability of naloxone for law enforcement and other first responders; form an interagency task force to develop best practices for pain management with opioid medications; and provide resources to improve state monitoring of controlled substances, including opioids. In 2018, CARA 2.0 was introduced as follow-up legislation to limit initial prescriptions for opioids to 3 days, while exempting initial prescriptions for chronic care, cancer care, hospice or end of life care, and palliative care.

- Enactment of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("*SUPPORT Act*"): In November 2018, the SUPPORT Act was enacted as a comprehensive legislative response to the continuing opioid epidemic. It includes a number of measures directed towards regulation and improvement of treatment for substance use-disorder and increased coverage by CMS of medically assisted treatment options. In addition, the SUPPORT Act requires HHS to report to Congress on existing barriers to access to abuse-deterrent opioid formulations by Medicare Part C and D beneficiaries. It also includes a number of requirements directed at reducing the potential for oversupply of opioids to reduce the potential for misuse and diversion.

Human Capital Resources

As of December 31, 2021, we had six full-time employees and six consultants. Of these, five have a Ph.D. and two have an M.B.A. From time to time, we also retain independent contractors to support our organization. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good. We intend to add additional full-time employees along with additional clinical support staff in 2022, and to expand our commercial sales force beginning 2023.

In July 2021 Ensysce appointed David J. Kovacs to a new position of VP Public Policy and David Tanzer to a new position of VP Strategic Development. Mr. Kovacs has extensive experience shaping policy and setting strategy for disruptive companies in pharmaceutical and technology sectors. He has served in various roles for public companies, including Vinco Ventures (NASDAQ: BBIG) and AudioEye, Inc. (NASDAQ: AEYE). Previously, Mr. Kovacs held senior roles in private equity and investment banking, including at Blackstone Group, Citigroup, and the Hinduja Group. Mr. Tanzer is an accomplished business executive specializing in helping companies with innovative intellectual property and technology maximize their potential. He has 25 years of diverse experience in the healthcare and media sectors, including as CEO or President of eight companies, service on nine company boards, and working at private equity firms, including Lee Equity Partners and Elevation Partners. Mr. Tanzer previously was President of PDR Network, publisher of the Physicians' Desk Reference, the authoritative source of drug safety information for prescribers.

Dr. Linda Pestano joined Ensysce in October 2021, as Chief Development Officer. Dr. Pestano has worked throughout her career to guide the development of novel therapeutics to improve patient outcomes and quality of life. Dr. Pestano received her PhD from Tuffs University and undertook a Post-Doctoral Fellowship with Dana Farber Cancer Institute at the Harvard Medical School in Boston. She has been instrumental in guiding new therapies, including small molecules, nucleic acids, and biologicals through development into clinical trials. Dr. Pestano's expertise spans lead development, pre-clinical and translational studies, and interacting with multiple regulatory agencies. Dr. Pestano joins Ensysce with 20 years of experience developing vaccines, drugs and novel biologics for a diverse range of indications.

Identification of Our Executive Officers

The Company's Executive Officers and their age and position are below.

Name	Age*	Officer Since	Position
Dr. Lynn Kirkpatrick, Ph.D	65	2009	President, Chief Executive Officer and Class III Director
Geoffrey Birkett	59	2018	Chief Commercial Officer
David Humphrey, CPA	53	2021	Chief Financial Officer, Secretary and Treasurer
Dr. Jeffrey Millard, Ph.D.	46	2019	Chief Operating Officer
Dr. Linda Pestano, Ph.D.	53	2021	Chief Development Officer
Dr. William Schmidt, Ph.D.	70	2016	Chief Medical Officer
Richard Wright, MBA	49	2016	Chief Business Officer

*Ages presented as of December 31, 2021

Dr. Lynn Kirkpatrick, Ph.D. has served as our Chief Executive Officer since January 2009. Dr. Kirkpatrick has spent over 30 years in drug discovery and development, has initiated the clinical development of four novel drug candidates and now strives to bring highly novel and safe pain therapies to commercialization. She received a Doctor of Philosophy ("*Ph.D.*") degree in Medicinal and Biomedicinal Chemistry at the University of Saskatchewan, completed a Post-Doctoral Fellowship at the Yale University School of Medicine, and became a tenured full professor in the Department of Chemistry at the University of Regina. She co-founded ProlX Pharmaceuticals, Corp. ("*ProlX*") an oncology discovery company, becoming Chief Executive Officer and successfully bringing three small molecules from discovery into clinical development, two of these her own discoveries from academia. ProlX was acquired by Biomira Inc., and Dr. Kirkpatrick became the Chief Scientific Officer of the merged company to focus on the development of oncology products and vaccines. In 2009, she co-founded PHusis Therapeutics, developing targeted small molecule precision medicines for oncology. At the same time, she became our Chief Executive Officer. Dr. Kirkpatrick has published extensively in the area of targeted drug discovery, abuse deterrent pain products and holds numerous patents for novel drugs and modalities. We believe Dr. Kirkpatrick is qualified to serve on our Board because of her extensive executive experience in our industry and her service as our Chief Executive Officer.

Geoffrey Birkett has served as our Chief Commercial Officer since October 2018. He has over 30 years of experience in the Pharmaceutical and Biotechnology area. He started his career as a biochemist at the Royal Victoria Infirmary in Newcastle-upon-Tyne, England. He then moved into the pharmaceutical industry, where he focused on pain/addiction and neuroscience throughout his career. He has developed and launched several groundbreaking therapies, including Nicorette (POM) and (OTC), Lexapro and several other psychiatry agents with Lundbeck. Mr. Birkett assisted on the launch of Prozac and Humatrope (human growth hormone) with Eli Lilly. He assisted in moving Seroquel from Phase 2 to global market leader with multi-billion dollar sales and he also participated in the launch of Zomig for migraines, which became a European market leader. He worked for most of his pharmaceutical career at AstraZeneca plc in both the United Kingdom and the United States, where he held many roles including overseeing the global oncology division. When the AstraZeneca merger took place, Mr. Birkett ran the merger process outside the United States across all markets, and ran a corporate change program to streamline research and development involving 67,000 staff. Since leaving AstraZeneca, Mr. Birkett has held multiple roles in biotech companies as senior officer or as a consultant. He is co-founder of a novel drug delivery company and has consulted for IPSOS, a large global research and consulting firm. He also served as president for North America/Canada of INDIVIOR, a large company producing addiction treatment drugs. Mr. Birkett joined us in 2018 and is focused on building a world class commercial team. Mr. Birkett attended Henley Business College in London and INSEAD Business School in France where he studied general management and a global leadership.

David Humphrey, CPA has served as our Chief Financial Officer since February 2021. Prior to joining the Company, Mr. Humphrey was most recently Chief Financial Officer of Senomyx, Inc. ("Senomyx"), a publicly held biotechnology company focused on taste science. In his previous employment, he guided public company financial reporting, including Forms 10-K, 10-Q, 8-K, S-3, S-8, proxy statements and SOX internal controls compliance, and acted as primary liaison with the audit committee and external auditors. Mr. Humphrey advised Senomyx's board of directors, as part of core executive management team, in a $75 million acquisition by Firmenich SA, a private Swiss multinational flavor and fragrance company. Previously, he held finance and accounting leadership positions and consulted at numerous life sciences companies, including ActivX Biosciences, Aurora Biosciences and Gensia. Mr. Humphrey started his career as an accountant at Price Waterhouse. He holds a Bachelor of Science with Honors in Accountancy from the University of Illinois at Urbana-Champaign and is a Certified Public Accountant in California.

Dr. Jeffrey Millard, Ph.D. has served as our Chief Operating Officer since January 2019. Dr. Millard has both academic and industrial experience in chemistry and pharmaceutical sciences covering all aspects of chemistry, manufacturing, and controls, or CMC. He has been involved in both start-up biotech as well as small and mid-sized public biopharmaceutical companies. Dr. Millard has been directly responsible for research and development activities and writing of more than seven IND submissions and Investigational Medicinal Product Dossiers, or IMPDs. He has directed the CMC efforts from discovery and in-licensing through commercial launch activities. His experience covers the application programming interface, or API, lifecycle (from synthetic route scouting, process chemistry, analytical chemistry development and validation, cGMP production and release of API, to QbD and process validation), and drug product development through manufacture. Dr. Millard received a Bachelor of Arts from Rice University and a Ph.D. in Pharmaceutical Sciences from the University of Arizona.

Dr. Linda Pestano, Ph.D. see "*Human Capital Resources*" for Dr. Pestano's biographical information.

Dr. William K. Schmidt, Ph.D., has served as our Chief Medical Officer since January 2016. He is also the Head of NorthStar Consulting, the Parliamentarian and a former president of the Eastern Pain Association, the largest regional affiliate of the American Pain Society. He has over 25 years of pharmaceutical industry experience with a special emphasis on the discovery and development of novel analgesic and narcotic antagonist drugs. He was previously Vice President of Clinical Development for CrystalGenomics (Seoul, South Korea) and its United States subsidiary, CG Pharmaceuticals (Emeryville, CA); Senior Vice President of Development at Limerick BioPharma; Vice President, Clinical Research, for Renovis, Inc.; and Vice President, Scientific Affairs and acting Vice President, Clinical Research and Development, at Adolor Corporation. At Adolor Corporation, Dr. Schmidt was a key member of the team leading to the clinical development, NDA filing, and FDA approval of Entereg® (alvimopan), a peripherally acting opioid antagonist. Currently Dr. Schmidt serves as an expert on pain medicine pharmaceutical development with pharmaceutical and biotech companies throughout North America, Europe, Asia, Latin America, and Australia. Dr. Schmidt received a Bachelor of Arts degree from the University of California Berkeley and his Ph.D. University of California-San Francisco.

Richard Wright MSE, MBA has served as our Chief Business Officer since January 2016. Mr. Wright is the Chief Executive Officer of Magnostics, Ltd, a superparamagnetic nano-material company based in Dublin, Ireland. Previously, he served as Venture Partner at Ren Capital Partners ("*Ren Capital*"), a healthcare fund of funds based in Beijing. Prior to Ren Capital, he was a strategic advisor to Bangkok Dusit Medical Service, the largest healthcare conglomerate in Southeast Asia, assisting in drug commercialization efforts. Mr. Wright was Managing Director at Newstock Capital, an intellectual property investment advisory firm based in Stockholm, Sweden. While at Newstock, he worked with venture capital and corporate funds on divestitures, mergers and acquisitions, patent transactions, licensing and infringement. Previously Mr. Wright was fund manager for General Electric / Technology Ventures where he managed an intellectual property healthcare fund. He was the Co-Founder and Chief Executive Officer of TherimuneX, a company that has been developing endogenous lipopeptides for their immune regulating properties. Mr. Wright was principal of Guardian Technology Partners, a chemical and life sciences intellectual property advisory firm that was sold to investment bank Boenning and Scattergood. Mr. Wright started his career on the business development team of Endo Pharmaceuticals, plc. Mr. Wright has over 24 years of experience spanning start-up, fast growth pharmaceutical companies combined with intellectual property and healthcare investment acumen from varied international markets. Mr. Wright holds a Master of Science in Engineering, Management of Technology with a focus of biotechnology from University of Pennsylvania's School of Engineering and Applied Sciences and Wharton School of Business, and a Master of Business Administration from London School of Economics TRIUM program.

Item 1A. Risk Factors

Risks Related to Our Business, Financial Condition and Capital Requirements

We are a clinical-stage pharmaceutical company with a limited operating history. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.

We are a clinical-stage pharmaceutical company with a limited operating history. We have not yet demonstrated an ability to generate revenues, obtain regulatory approvals, engage in clinical development beyond Phase 1 trials, manufacture any product on a commercial scale or arrange for a third party to do so on our behalf or enter into licensing arrangements to commercialize a product, or conduct sales and marketing activities necessary for successful product commercialization.

We have no products approved for commercial sale and we have not generated any revenue from product sales to date, nor do we expect to generate any significant revenue from product sales for the next few years. We will continue to incur significant research and development and other expenses related to our product development, preclinical and clinical activities and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net loss was $29.1 million for the year ended December 31, 2021. As of December 31, 2021, we had an accumulated deficit of $85.8 million. We expect to continue to incur significant losses for the foreseeable future as we continue our research and development of, and seek regulatory approvals for, our product candidates.

If we continue to suffer losses as we have since inception, investors may not receive any return on their investment and may lose their entire investment.

In addition, as a public company, we incur significant additional legal, accounting and other expenses that we did not incur as a private company as we:

- meet the requirements and demands of being a public company;
- expand our operational, financial and management systems and increases personnel to support our operations;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support our clinical operations;
- advance our clinical-stage product candidate PF614 through clinical development;
- advance our preclinical stage product candidates into clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;

- undertake any pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own or jointly with third parties;

- maintain, expand and protect our intellectual property portfolio; and

- make milestone, royalty or other payments due under any future in-license or collaboration agreements.

Pharmaceutical product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable. Therefore, any investment in us would be highly speculative. Our prospects are subject to the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage pharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We will likely encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

Additionally, our expenses could increase beyond our expectations if we are required by the United States Food and Drug Administration, or FDA, or other regulatory authorities to perform clinical trials in addition to those that we currently expect to conduct, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials or the development of any of our product candidates.

Our ability to generate revenue from any of our potential products is subject to our ability to obtain regulatory approval and fulfill numerous other requirements and we may never be successful in generating revenues or becoming profitable.

Our ability to become and remain profitable depends on our ability to generate revenue or execute other business development arrangements. We do not expect to generate significant revenue, if any, unless and until we are able to obtain regulatory approval for, and successfully commercialize the product candidates we are developing or may develop. Successful commercialization, to the extent it occurs, will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling, or entering into other agreements to commercialize, those products for which we may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we cannot accurately and precisely predict the timing and amount, if any, of revenues, the extent of any further losses or when we might achieve profitability. We may never succeed in these activities and, even if we do, we may never generate revenues that are sufficient enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

We require substantial additional funding. If we are unable raise capital when needed, we could be forced to delay, reduce or terminate our product discovery and development programs or commercialization efforts.

We are a clinical stage pharmaceutical company that will need to raise additional capital to continue to operate as a going concern. Our quarterly operating results are likely to show continued losses in the future. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical and preclinical development of our product candidates, including our planned Phase 2 program for nafamostat and planned clinical trials for PF614 and PF614-MPAR™. We will need to raise additional capital to complete our currently planned clinical trials and any future clinical trials. Other unanticipated costs may arise in the course of our development efforts. If we are able to obtain marketing approval for product candidates that we develop, we would require significant additional amounts of funding in order to launch and commercialize such product candidates. We cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop and we may require substantial additional funding to complete the development and commercialization of our product candidates.

Our future need for additional funding depends on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future, including the costs related to preclinical and clinical development of the product;

- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any other additional product candidates we may develop and pursue in the future;
- the number of future product candidates that we may pursue and their development requirements;

- subject to receipt of regulatory approval, the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;

- subject to receipt of regulatory approval, the amount of revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future;

- the extent to which we in-license or acquire rights to other products, product candidates or technologies;

- our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all;

- our headcount growth and associated costs as we expand our research and development and establishes a commercial infrastructure;

- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and

- the costs of operating as a public company.

A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate, and many of these factors are outside of our control. Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory and marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. We cannot be certain that additional funding will be available on acceptable terms, or at all. Please see the risk factors under "*Risks Related to the Ownership of Common Stock and Financial Reporting*."

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through the third quarter of 2022, while continuing to advance our main product candidates, such as PF614 and PF614 MPAR™, through clinical development. Our estimate may prove to be wrong, and we could use our available capital resources, if any, sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. To the extent this occurs, it could impose significant dilution on our stockholders.

We may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our platforms, programs, planned clinical trials or future commercialization efforts.

We may incur additional dilution upon repayment of the 2021 Notes with common stock.

Under the terms of the SPA, we are permitted to repay principal and interest on the 2021 Notes by issuing additional shares of common stock. In addition, the conversion price of the 2021 Notes, and the exercise price of the warrants issued therewith, are subject to downward revision in the event we make certain issuances of our common stock at prices below the conversion price. We have registered shares of common stock under a Registration Statement on Form S-1 in the event either of these events occur. In such case, stockholders will have dilution in amounts exceeding the straight conversion of the 2021 Notes or, with respect to the warrants issued therewith, we will receive a reduced level of proceeds from the exercise of the warrants.

The price of our common stock on the Nasdaq and Public Warrants on the OTC Pink Open Market may be volatile.

The price of our common stock on the Nasdaq and our Public Warrants on the OTC Pink Open Market may fluctuate due to a variety of factors, including:

- changes in the industries in which we and our customers operate;
- variations in our operating performance and the performance of our competitors in general;
- material and adverse impact of the COVID-19 pandemic on the markets and the broader global economy;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- publication of research reports by securities analysts about us, our competitors or our industry;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;

- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving us;
- news about, among other things, the results of our clinical trials or other developments, or the use or abuse of opioids,
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- sales, or anticipated sales, of large blocks of our common stock;
- the volume of shares of our common stock available for public sale; and
- general economic and political conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks and acts of war or terrorism.

These and other factors, many of which are beyond our control, may cause the market price and demand for our shares of common stock to fluctuate substantially. Low trading volume could increase the volatility of our share price in response to news in the market, could prevent investors from readily selling their shares and may otherwise negatively affect the market price and liquidity of our shares. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management from our business, which could significantly harm our profitability and reputation.

The proceeds under the GEM Agreement may be less than anticipated. The issuances of common stock pursuant to the GEM Agreement would result in dilution of existing stockholders and could have a negative impact on the market price of our common stock. Additionally, the negative covenants under the GEM Agreement are onerous and any breach by us thereunder may entitle GEM Global and GYBL to indemnification payments, reimbursements of legal and other expenses and other compensation thereby diverting our time and resources.

We are entitled to draw down up to $60.0 million of gross proceeds from GEM Global in exchange for shares of our common stock at a price equal to 90% of the average closing bid price of the shares of our common stock on Nasdaq for a 30-day period, subject to meeting the terms and conditions of the GEM Agreement. This share subscription facility is available for a period of 36 months from the closing date of the Merger. Please see the section entitled "*Business*" for additional information. The limitations on the amount and frequency of the draws that we can make under the GEM facility, which include the requirement that (i) there be an effective registration statement and (ii) size restrictions relating to our trading volume, may affect the ability to draw under the GEM Agreement and result in proceeds that are less than anticipated. In addition, while the 2021 Notes are outstanding, any draws under the GEM facility would require approval from the convertible note holders.

The occurrence of the Merger triggered (i) payment of a commitment fee of $1.2 million to GEM Global payable in either our common stock or cash and (ii) the issuance of a warrant granting GYBL the right to purchase 1,106,108 shares of our common stock, at a strike price per share of $10.01, the closing bid price for such common shares on the closing date of the Merger. The number of shares underlying the warrant as well as the strike price is subject to adjustments for recapitalizations, reorganizations, change of control, stock split, stock dividend, reverse stock splits and certain issuances of additional shares of our common stock.

The issuances of shares at discount under the GEM Agreement and the anti-dilution protection granted to GEM Global in connection with issuances of additional shares of our common stock, would result in dilution of existing stockholders and have a negative impact on the market price of our common stock and our ability to obtain equity

financing. An adjustment in the price of the GEM Warrant to $4.50 occurred in connection with our offering of the 2021 Notes. In addition, terms of the 2021 Notes currently limit our ability to draw on the GEM facility while the 2021 Notes remain outstanding.

In addition, the negative covenants under the GEM Agreement are onerous and any breach thereof may trigger indemnification, reimbursement of losses and other liability for us thereby diverting our time and resources.

Raising additional capital could cause dilution to our stockholders, adversely affect the market price of our common stock, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenues, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder.

In addition, we may sell securities in the public or private equity markets if and when conditions are favorable, or at prices per share below the current market price of our common stock, even if we do not have an immediate need for additional capital at that time. Sales of substantial amounts of shares of our common stock, or the perception that such sales could occur, could adversely affect the prevailing market price of our shares and our ability to raise capital. We may issue additional shares of common stock in future financing transactions or as incentive compensation for our executive management and other key personnel, consultants and advisors. Issuing any equity securities would be dilutive to the equity interests represented by our then-outstanding shares of common stock. Moreover, sales of substantial amounts of shares in the public market, or the perception that such sales could occur, may adversely affect the prevailing market price of our common stock and make it more difficult for us to raise additional capital.

Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions, engaging in acquisition, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or intellectual property, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.

Our future success and ability to generate significant revenue from our product candidates, which we do not expect will occur for several years, is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our product candidates. A Phase 1b study of PF614 was initiated in 2021, and Part A of the study completed enrollment in December 2021. A Phase 1 trial was also initiated for PF614-MPAR™ in December 2021. All of our other product candidates are in earlier stages of development and will require substantial additional investment for manufacturing, preclinical testing, clinical development, regulatory review and approval in one or more jurisdictions. If any of our product candidates encounter safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed.

We may not have the financial resources to continue development of our product candidates. Even if clinical trials are completed, we may experience other issues that may delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective;
- insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates that are similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- product-related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidates;
- delays in submitting an Investigational New Drug application, or IND, or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced;
- conditions imposed by the FDA, the European Medicines Agency, or EMA, or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- poor effectiveness of our product candidates during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- delays in enrolling subjects in clinical trials;
- high drop-out rates of subjects from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial or manufacturing costs;
- unfavorable FDA, EMA or comparable regulatory authority inspection and review of a clinical trial site;

- failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all;

- unfavorable FDA, EMA or comparable regulatory authority inspection and review of manufacturing facilities or inability of those facilities to maintain a compliance status acceptable to the FDA, EMA or comparable regulatory authorities;

- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or

- varying interpretations of data by the FDA, EMA and comparable foreign regulatory authorities.

Our product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that such product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure stockholders that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

We depend heavily on the success of our lead product candidate PF614, which is currently in clinical trials. Our clinical trials of PF614 may not be successful. If we are unable to commercialize PF614 or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the research and development of our lead product candidate, PF614 and we expect to continue to do so. Our ability to generate revenues from the sale of abuse-deterrent opioid products, which may not occur at a significant level for several years, will depend heavily on the successful development, regulatory approval and eventual commercialization of PF614.

We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from similar regulatory authorities outside of the United States. Even if PF614 or another product candidate were to successfully obtain approval from the FDA and non-U.S. regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for PF614 in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development, marketing and/or commercialization of PF614 or any other product candidate that we may discover, in-license, develop or acquire in the future. Furthermore, even if we obtain regulatory approval for P614, we will still need to develop a commercial organization, or collaborate with third parties for the commercialization of PF614, establish commercially viable pricing and obtain approval for adequate reimbursement from third-party and government payors. If we or our commercialization collaborators are unable to successfully commercialize PF614, we may not be able to generate sufficient revenues to continue our business.

Due to the significant resources required for the development of our product pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.

We currently have three clinical-stage product candidates as well as certain other product candidates that are at various stages of preclinical development. We seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively pursuing our more advanced clinical-stage product candidates, such as nafamostat, PF614 and PF614-MPAR™, and ensuring the development of additional potential product candidates.

Due to the significant resources required for the development of our product candidates, we must focus on specific diseases and disease pathways and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misinterpret trends in the pharmaceutical industry, in particular for opioid abuse and drug overdose, our business, financial condition, and results of operations could be materially adversely affected. As a result, we may (i) fail to capitalize on viable commercial products or profitable market opportunities, (ii) be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or (iii) relinquish valuable rights to such product candidates through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

Our PF614 and PF614-MPAR™ product candidates may not be successful in limiting or impeding abuse, overdose or misuse or providing additional safety upon commercialization.

We are committing a substantial majority of our resources to the development of products utilizing our TAAP and MPAR™. There can be no assurance that our products will perform as tested and limit or impede the actual abuse, overdose or misuse of such products or provide other benefits in commercial settings. Moreover, there can be no assurance that if our products are approved by the FDA, the post-approval epidemiological studies required by the FDA as a condition of any such approvals of the products will show a reduction in the consequences of abuse and misuse by patients for whom the applicable product is prescribed. The failure of our products to limit or impede actual abuse, overdose or misuse or provide other safety benefits in practice will have a material adverse impact on market acceptance for such products and on our financial condition and results of operations.

If we fail to discover, develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired. In addition, we may also seek to commercialize certain treatments that may not be proprietary to us.

Although the development and commercialization of our current product candidates are our initial focus, as part of our long-term growth strategy, we plan to develop other product candidates. We may also seek to commercialize treatments that may not be proprietary to us. We intend to evaluate internal opportunities from our existing product candidates or other potential product candidates. While our technology platforms have potential applicability to other uses, we have not conducted any clinical trials on these other uses, and we may not be successful in developing product candidates for other uses.

In addition, we intend to devote capital and resources for basic research to discover and identify additional product candidates. These research programs require technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;

- competitors may develop alternatives that render our product candidates obsolete;
- product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

In the future, we may also seek to in-license or acquire product candidates or the underlying technology. The process of proposing, negotiating and implementing a license or acquisition is lengthy and complex. Other companies, including many with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;

- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

If we are unsuccessful in identifying and developing additional product candidates, either through internal development or licensing or acquisition from third parties, our potential for growth and achieving our strategic objectives may be impaired.

If we do not achieve our projected development and commercialization goals within the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

For planning purposes, we seek to estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The potential achievement of many of these milestones may be outside of our control. Each of these milestones is based on a variety of assumptions which, if not realized as expected, may cause the timing of such potential achievement of the respective milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other regulatory authorities and the timing thereof;
- clinical outcomes;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used in the manufacture of our product candidates;
- the efforts of our collaborators with respect to the commercialization of our product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve any announced milestones in the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed, and it could negatively impact our share price performance. Please see "*Business*" for more information.

Competitive products may reduce or eliminate commercial opportunity for our product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than any such technologies or product candidate of ours, our ability to develop and successfully commercialize our own technologies or product candidates may be adversely affected.

The clinical and commercial landscapes for the solution of opioid abuse and drug overdose are highly competitive and subject to rapid and significant technological change. We face competition with respect to our indications for our product candidates and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a

number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of product candidates for the treatment of the indications that we are pursuing. These companies include, but are not limited to, Purdue Pharma, LP, and Collegium Pharmaceutical, Inc. Potential competitors include not only pharmaceutical companies but also academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We believe that a significant number of product candidates are currently under development for the same indications that we are currently pursuing, and some or all may become commercially available in the future for the treatment of conditions for which we are trying or may try to develop product candidates. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. See the section entitled "*Business — Competition*" for examples of the competition that our product candidates face.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than us. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our therapies obsolete or non-competitive before we can recover development and commercialization expenses. If any of our product candidates, including PF614, is approved, these product candidates could compete with a range of therapeutic treatments that are in development. In addition, our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective or less costly than PF614, our other product candidates or any other product candidates that we may develop, which could render our product candidates obsolete and noncompetitive.

If we obtain approval for any of our product candidates, we may face competition based on many different factors, including the efficacy, safety and tolerability of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Existing and future competing products could present superior treatment alternatives, including being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop.

Competitive products may make any products we develop obsolete or noncompetitive before we are able to recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

In addition, our competitors may obtain patent protection, regulatory exclusivities or FDA approval and commercialize products more rapidly than we do, if we are successful at all, which may impact future approvals or sales of any of our product candidates that receive regulatory approval. If the FDA approves the commercial sale of PF614 or any other product candidate, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect any such competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product candidates receive regulatory approval but cannot compete effectively in the marketplace.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our business could be harmed if we lose the services of our key personnel or if we are unable to hire additional highly qualified employees.

Our business depends upon our ability to attract and retain highly qualified personnel, including managerial, sales and technical personnel. We compete for key personnel with other companies, healthcare institutions, academic institutions, government entities and other organizations. We do not have written employment agreements with our Chief Executive Officer. Our ability to maintain and expand our business may be impaired if we are unable to retain our current key personnel or hire or retain other qualified personnel in the future.

We currently only have six full-time employees and six consultants and we expect to add additional employees. Our future success also depends on our ability to identify, attract, hire or engage, retain and motivate other well-qualified managerial, technical, clinical and regulatory personnel.

Competition for such individuals, particularly in the United States, is intense, and we may not be able to hire sufficient personnel to support our efforts. There can be no assurance that such professionals will be available in the market, or that we will be able to retain existing professionals or to meet or to continue to meet their compensation requirements. Furthermore, our cost base with respect to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on our financial results, including the potential for additional dilution to our stockholders. Failure to establish and maintain an effective management team and work force could adversely affect our ability to operate, grow and manage our business.

Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that we and our contract research organizations' ("*CROs*") employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations

Some of our programs are partially supported by government grant awards, which may not be available to us in the future.

We have received funding under grant award programs funded by governmental agencies, such as the NIH and NIDA. To fund a portion of our future research and development programs, we may apply for additional grant funding from these or similar governmental agencies in the future. However, funding by these, and other, governmental agencies may be significantly reduced or eliminated in the future for a number of reasons. For example, some programs are subject to a yearly appropriations process in Congress. In addition, we may not receive full funding under current or future grants because of budgeting constraints of the agency administering the program or unsatisfactory progress on the study being funded. Also, the continued spread of COVID-19 could affect governmental priorities in the future or prospective funding for our

product candidates. Therefore, we cannot provide any assurance that we will receive any future grant funding from any government agencies, or, that if received, we will receive the full amount of the particular grant award. Any such reductions could delay the development of our product candidates and the introduction of new products.

We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience growth in the number of our employees and the scope of our operations. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of their attention to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

Risks Related to Our Dependence on Third-Party Providers

We currently rely on, and expect to rely on in the future, third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for completing such trials, failing to satisfy legal or regulatory requirements or terminating the relationship.

We currently rely on, and expect to rely on in the future, third-party CROs to conduct research and development activities and our clinical trials for our product candidates. Agreements with these CROs might terminate for a variety of reasons, including for their failure to perform. Entry into alternative arrangements, if necessary, could significantly delay our product development activities.

Our reliance on these CROs for research and development activities and clinical trials will reduce our control over these activities but will not relieve us of any of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols in the applicable IND. Moreover, the FDA requires compliance with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

If these CROs do not successfully carry out their contractual duties, meet expected deadlines or conduct the clinical trials in accordance with regulatory requirements or our stated protocols, it could adversely affect the development of our product candidates and it could result in us not being able to obtain, or being delayed in obtaining, marketing approvals for our product candidates and it could adversely affect our efforts to successfully commercialize our product candidates.

We expect to be completely dependent on third parties to manufacture our product candidates, and our commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to maintain a compliance status acceptable to the FDA or comparable foreign regulatory authorities, fail to provide to us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the ingredients in our product candidates for use in our clinical trials or for commercial product, if any. We have entered into a Manufacturing Agreement (the "*Recro Agreement*") with Recro Gainesville LLC ("*Recro*") for the production of PF614 capsules and other materials and services with respect to our clinical studies. In addition, we do not have the capability to encapsulate any of our product candidates as a finished product for commercial distribution. As a result, we expect to be obligated to rely on contract manufacturers, like Recro, if and when any of our product candidates are approved for commercialization. In the event that Recro is unable to perform its obligations under the Recro Agreement, we may be unable to replace the Recro Agreement on terms as favorable to us. We have not entered into an agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of any of our product candidates on favorable terms to us, or at all.

The processes used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or comparable foreign regulatory authorities and the facilities at which the product candidates are manufactured must maintain a compliance status acceptable to the FDA and foreign regulatory authorities. FDA and foreign regulatory authorities will conduct inspections after we submit a new drug application, or NDA, to the FDA or its equivalent to other relevant regulatory authorities. We will not control the manufacturing process of, and will be completely dependent on, its contract manufacturing partners for compliance with cGMPs for manufacture of both active drug substances and finished products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. If our contract manufacturers, including Recro, do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, our product candidates may not be approved. If these facilities do not maintain a compliance status acceptable to the FDA, Drug Enforcement Agency, or DEA, or comparable regulatory authorities, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Our contract manufacturers, including Recro, will be subject to ongoing periodic unannounced inspections by the FDA, DEA and corresponding state and foreign agencies for compliance with cGMPs, security, recordkeeping and similar regulatory requirements. Although we will not have control over our contract manufacturers' compliance with these regulations and standards, we are nonetheless responsible for assuring such compliance. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our product candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and results of operations. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market any of our product candidates.

If, for any reason, these third parties, including Recro, are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our ingredients or finished products or should cease doing business with us, we could experience significant interruptions in the supply of any of our product candidates or may not be able to create a supply of our product candidates at all. Our inability to coordinate the efforts of our third-party manufacturing partners, or the lack of capacity available at our third-party manufacturing partners, could impair our ability to supply any of our product candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of any of our product candidates if we decide to transfer the manufacture of any of our product candidates to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer, including Recro, could be disruptive to our operations and delay development of our investigational products. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a

future contract manufacturer caused by problems at suppliers could delay shipment of any of our investigational products and, if approved, product candidates.

We cannot guarantee that our future manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of any of our product candidates over time. If the commercial-scale manufacturing costs of any of our product candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities.

We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.

We currently have no marketing, sales or distribution capabilities. We intend to establish a sales and marketing organization, either on our own or in collaboration with third parties, with technical expertise and supporting distribution capabilities to commercialize PF614 or one or more of our other product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of PF614, our other product candidates and other future product candidates.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, we have not submitted an NDA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for our most advanced product candidate, PF614, or any other product candidate. We must complete additional preclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our initial and potential additional product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements, and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if any of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials, we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events, or SAEs, or other adverse effects, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for our proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with the manufacturing processes of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in us failing to obtain regulatory approval to market any product candidate we develop, which would substantially harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with labeling that does not include the claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

The FDA may recommend scheduling with respect to any of our current or future product candidates. In such event, prior to a product launch, the DEA will need to determine the controlled substance schedule of the product, taking into account the recommendation of the FDA. The timing of the scheduling process is uncertain and may delay our ability to market any product candidate that we successfully developed and approved.

The FDA has the authority to grant an Emergency Use Authorization ("*EUA*") to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when, based on the totality of scientific evidence, there is evidence of effectiveness of the medical product, and there are no adequate, approved, and available alternatives. Based on the outcomes of our clinical testing for nafamostat, Ensysce expects to apply for an EUA for use against coronaviral infections, which would permit us to commercialize nafamostat prior to FDA approval of an NDA. However, commercialization under an EUA is permitted only during the period of time that FDA determines that the statutory criteria for EUA are met, meaning that we would be required to obtain NDA approval to continue marketing the product. Furthermore, the FDA may revoke an EUA based on a determination that the product no longer satisfies the criteria for issuance of an EUA—for example, if there is no longer evidence of effectiveness of the product or there are other adequate, approved alternatives. Accordingly, we cannot predict how long, if at all, an EUA for nafamostat or any other product candidates may remain in place. Any termination or revocation of an EUA (if any) for nafamostat or any other product candidates could adversely impact our business in a variety of ways, including if nafamostat is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide nafamostat under an EUA.

If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for, or commercialize our product candidates.

The results observed from preclinical studies or early-stage clinical trials of our product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from such preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. For example, preclinical studies showed that PF614 does not readily convert into oxycodone in the blood stream and the Phase 1 trial we have conducted with TAAP prodrug (a medication or compound that, after administration, is metabolized (i.e., converted within the body) into a pharmacologically active drug, or "prodrug") PF614, demonstrated that, after oral administration of the TAAP prodrug, the corresponding opioid was measured in the subjects' blood. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as other product candidates that we believe may have similar profiles.

There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable foreign regulatory authority approval.

The FDA, EMA or comparable foreign regulatory authorities may disagree with our regulatory plan for our product candidates.

We have submitted IND applications for PF614 and nafamostat and completed a Phase 1 trial for each product candidate. We have applied for and received fast track designation for PF614. However, fast track designation does not guaranty a faster development or regulatory review or approval process and does not assure FDA approval. We have received feedback from the FDA on requirements to achieve abuse deterrent labeling claims for PF614. We have submitted an IND for PF614-MPAR™ and have received feedback on required pre-clinical, manufacturing and clinical studies that will be required for an NDA.

Our clinical trial results may not support approval of our product candidates. The general approach for FDA approval of a new drug is dispositive data from two or more well-controlled Phase 3 clinical trials of the product candidate in the relevant patient population. Phase 3 clinical trials typically involve a large number of patients, have significant costs, and take years to complete. In addition, there is no assurance that the endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. For example, while we have designed our Phase 2 clinical trials of nafamostat for coronaviral infections after receiving input and feedback from the FDA, there can be no assurance that the design of our planned clinical trials will be satisfactory to the FDA, the FDA will not require us to modify our trials, these trials will enable us to conduct the required Phase 3 studies or other testing or that completing these trials will result in regulatory approval.

Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data is available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates.

Any product candidate we develop and the activities associated with such development and commercialization, including our design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the

product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval. Ensysce has no experience in submitting and supporting the applications necessary to gain marketing approvals and we expect to rely on third-party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and requires additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. For example, during the product approval process, the FDA will determine whether a REMS plan is necessary to assure the safe use of the product. All opioid analgesic products currently on the market in the United States are subject to a REMS. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care providers of the risks, limitations on who may prescribe or dispense the drug or other measures that the FDA deems necessary to assure the safe use of the drug. In addition, the REMS plan must include a timetable to assess the strategy at eighteen months, three years and seven years after approval. We may be required to develop a REMS for the product, or participate in a REMS with other manufacturers, or to develop a similar strategy as required by a regulatory authority.

Even if approved, our contract manufacturers will need to obtain quota from DEA to manufacture sufficient quantities and maintain inventories of product to be commercially distributed.

If we experience delays in obtaining manufacturing approval or if we fail to obtain manufacturing approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

Any product candidate for which we obtain marketing approval will be subject to ongoing enforcement of post-marketing requirements by regulatory agencies, and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, as well as the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping.

The FDA also may impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product, including the adoption and implementation of risk evaluation and mitigation strategies. The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Violations of such requirements may lead to investigations alleging violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients using our products;
- restrictions on such products, manufacturers or manufacturing processes;

- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal or recall of the product from the market;
- refusal to approve pending applications or supplements to approved applications that Ensysce submits;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of our products can also result in significant financial penalties.

Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting Ensysce from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the preclinical and clinical studies necessary for development and commercialization of our product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an IND, or not approving or delaying approval for any clinical trial grant or similar approval that we need to initiate a clinical trial. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators, or institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;
- the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipates;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to resubmit to an IRB and regulatory authorities for re-examination;
- regulators or other reviewing bodies may find deficiencies with or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Regulators or IRBs of the institutions in which clinical trials are being conducted may suspend, limit or terminate a clinical trial, or data monitoring committees may recommend that we suspend or terminate a clinical trial, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of our product candidates in such other indications. We do not know whether any clinical trials that we conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates for the indications that we are pursuing. If later-stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates will be adversely impacted.

Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would significantly harm its business. The development costs of our product candidates will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. We cannot assure stockholders that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with our protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the study until its conclusion.

We may experience difficulties in patient enrollment in our clinical trials for a variety of factors, including:

- the effects of COVID-19 on our ability to recruit and retain patients, including as a result of potential heightened exposure to COVID-19, prioritization of hospital resources toward the pandemic and unwillingness by patients to enroll or comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services;
- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Furthermore, if significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our trials and patients may drop out of our trials.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials or our development efforts altogether. Delays in patient enrollment may result in increased costs, negatively affect the timing or outcome of the planned clinical trials, delay the product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could cause our value to decline and limit our ability to obtain additional financing if needed.

Fast track designation by the FDA for PF614 may not lead to a faster development or regulatory review or approval process and does not assure FDA approval.

We have obtained fast track designation for PF614 that will enable us to facilitate the development and expedite the review of PF614. Fast track designation does not ensure that PF614 will receive marketing approval or that approval will be granted within any particular timeframe. As a result, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation does not guarantee that an NDA will obtain priority review designation. If any of these events occur, it could require us to conduct more extensive clinical trials and go through more extensive FDA review, which could substantially increase expenses and delay the time for commercializing our products.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We may seek FDA approval through the Section 505(b)(2) regulatory pathway for our product candidate PF614. Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDC Act, permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDC Act, would allow an NDA we submit to FDA to rely in part on data in the public domain or on the FDA's prior conclusions regarding the safety and effectiveness of an approved product, or listed drug, which could expedite the development program for our product candidates by potentially decreasing the amount of data that we would need to generate in order to obtain FDA approval. If the FDA does not agree that the 505(b)(2) regulatory pathway is appropriate or scientifically justified for PF614, we may need to conduct additional preclinical and clinical trials, provide additional data and information, and meet additional standards for regulatory approval. For example, the FDA may not agree that we have provided a scientific bridge, through, for example, comparative bioavailability data, to demonstrate that reliance on the prior findings of safety or efficacy for a listed drug is justified. If this were to occur, the time and financial resources required to obtain FDA approval for this product candidate, and complications and risks associated with this product candidate, would likely substantially increase. We could need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, the inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact of our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure our stockholders that our product candidates will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

If we submit a 505(b)(2) application that references a third-party product, we may be subject to a patent infringement suit and the approval of our product may be delayed.

If we submit a 505(b)(2) application that relies in whole or in FDA's findings for a listed drug, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, which we refer to as the Orange Book, with respect to the listed drug; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our product. A certification that our new drug will not infringe the Orange Book-listed patents for the applicable listed drug, or that such patents are invalid, is called a paragraph IV certification. If we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to the NDA holder once our 505(b)(2) application is filed by the FDA. The third party may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our 505(b)(2) application until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45-day period, our 505(b)(2) application will not be subject to the 30-month stay of FDA approval.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or repeating one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in restrictive warnings or contraindication or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. In our planned and future clinical trials of our product candidates, we may observe a less favorable safety and tolerability profile than was observed in earlier-stage testing of these candidates.

Undesirable side effects have been observed in our product candidates to date. For example, in clinical trials of PF614, opioid side effects were observed. Many compounds that initially showed promise in clinical or earlier-stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Results of future clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier-stage testing. If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which its trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that are administered our product candidates. Any of these occurrences may adversely affect our business, financial condition and prospects significantly.

Moreover, clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

Product liability lawsuits against us or any of our future collaborators could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of our product candidates.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the use of our product candidates by us and any collaborators in clinical trials, and the sale of these product candidates, if approved, in the future, may expose us to liability claims. We face an inherent risk of product liability lawsuits related to the use of our product candidates in patients and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers, pharmaceutical companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with

illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage consistent with industry norms, including clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business, financial condition, results of operations and prospects.

Oxycodone is a Schedule II controlled substance under the federal CSA, and any failure to comply with the CSA or its state equivalents would have a negative impact on our business.

Oxycodone, the ingredient in PF614, is classified as a Schedule II controlled substance under the Controlled Substances Act, or CSA and regulations promulgated by the DEA. The law and regulations classify substances as Schedule I, II, III, IV or V controlled substances, with Schedule I controlled substances considered to present the highest risk of substance abuse and Schedule V controlled substances the lowest risk. Scheduled controlled substances are subject to DEA regulations relating to supply, procurement, manufacturing, storage, shipment, sale, use, distribution and physician prescription procedures. For example, Schedule II controlled substances are subject to various restrictions, including, but not limited to, mandatory written prescriptions and the prohibition of refills. In addition to federal scheduling, oxycodone is subject to state-controlled substance laws and regulations, and in some cases, with additional requirements than those imposed by federal law and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may schedule products separately.

Entities must register annually with the DEA to manufacture, distribute, dispense, import, export and conduct research using controlled substances. In addition, the DEA requires entities handling controlled substances to maintain complete and accurate records and file reports, including reports related to thefts or losses of any controlled substances, and to obtain authorization to destroy any controlled substances. Registered entities also must follow specific labeling and packaging requirements. Facilities must maintain appropriate security measures to control against diversion of controlled substances. Security requirements vary by controlled substance schedule with the most stringent requirements applying to Schedule I and Schedule II controlled substances. Required security measures include background checks on employees and physical control of inventory through measures such as vaults and inventory reconciliations.

Our contract manufacturing organizations, or CMOs, who manufacture and distribute PF614 are required to be registered with DEA and relevant state authorities and comply with all security, recordkeeping and reporting requirements. Manufacturers and distributors are subject to routine inspections and audits by the DEA related to compliance with security, recordkeeping and reporting requirements. Failure to maintain the required registrations or to comply and follow these requirements can lead to significant civil and/or criminal penalties and possibly even lead to a revocation of a DEA registration to manufacture or distribute such products.

Manufacturing of oxycodone is subject to annual quotas that limit the amount of API and dosage forms that can be produced in any given year; the failure of our CMOs to obtain the necessary manufacturing and/or procurement quota would have a negative impact on our business.

The CSA and DEA regulations establish an annual aggregate production quota for Schedule I and II controlled substances, including oxycodone and other narcotic drugs. In addition, each manufacturer of active pharmaceutical ingredient, or API or dosage forms must obtain an individual manufacturing or production quota that limits the amount of product that a company can produce and/or distribute in a given year. The DEA allocates manufacturing quota issued to companies so as to not exceed the aggregate quota established for a given year. Moreover, companies must demonstrate the need for procurement quota based on expected demand and sales of the controlled substance the DEA requires the submission of substantial evidence of expected legitimate medical and scientific need for the drug product before assigning its aggregate production quotas, or manufacturing and procurement quotas to manufacturers. The DEA has decreased the aggregate quota for certain narcotic drugs, including oxycodone over the last five years. Also, in October 2018, Congress passed the SUPPORT Act which requires the DEA to consider potential diversion in establishing quotas for narcotic drugs which could lead to continued decreases in quota available to API manufacturers and dosage form manufacturers of these substances.

In future years, we may need greater amounts of controlled substances that are subject to the DEA's quota system to sustain our development program. We may also need significantly greater amounts to implement our commercialization plans if the FDA approves our proposed formulations. If any of our manufacturers of API or dosage forms are unable to obtain the necessary annual quota to meet the research and development or commercial demand for PF614, our business would be negatively impacted. Any delay or refusal by the DEA in establishing a quota, a reduction in quota, or a failure to increase quota over time could delay or stop the clinical development or commercial sale of some of our products or product candidates. This could have a material adverse effect on our business, results of operations, financial condition and prospects.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain patent protection for our products candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates that are similar or identical to our product candidates, and our ability to successfully commercialize our product candidates may be adversely affected.

Our commercial success will depend, in part, on our ability to obtain and maintain patent protection in the United States and other countries with significant commercial markets with respect to our product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates that are important to our business, as appropriate. We cannot be certain that patents will be issued or granted with respect to applications that are currently pending or that we may apply for in the future with respect to one or more of our product candidates, or that issued or granted patents will not later be found to be invalid and/or unenforceable.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we may enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, distribution partners, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued, and even if issued, the patents may not meaningfully protect our product candidates, effectively prevent competitors and third parties from commercializing competitive products or otherwise provide us with any competitive advantage. Even if the patent applications that we own or licenses issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. For product candidates for which we do not hold or do not obtain composition of matter patents, competitors who obtain the requisite regulatory approval can offer products with the same composition as our product candidate so long as the competitors do not infringe any method patents that we may hold. Method patents protect the product when used or sold for the specified method. However, this type of patent protection can be more difficult to enforce and does not limit a competitor from making and marketing a product that is identical to our product candidate that is either labeled or marketed for an indication that is outside of the patented method, or for which there is a substantial use in commerce outside the patented method. Our competitors or other third parties may be able to circumvent our patents by developing similar or

alternative products in a non-infringing manner.

Changes in either the patent laws, implementing regulations or interpretation of the patent laws in the United States and other countries may also diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions.

We cannot be certain that our patents and patent rights will be effective in protecting our product candidates and technologies. Failure to protect such assets may have a material adverse effect on our business, operations, financial condition and prospects.

We may face litigation from third parties claiming that our products or business infringe, misappropriate, or otherwise violate their intellectual property rights, or seeking to challenge the validity of our patents.

Our future success is also dependent in part on the strength of our intellectual property, trade secrets and know-how, which have been developed from years of research and development, and on our ability, and the ability of our future collaborators, to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technologies without alleged or actual infringement, misappropriation or other violation of the patents and other intellectual property rights of third parties.

We may be exposed to, or be threatened with, adversarial proceedings or additional future litigation by third parties regarding intellectual property rights with respect to our current and any future product candidates and technology, including interference or derivation proceedings, post grant review and inter partes review before the United States Patent and Trademark Office, or USPTO, or similar adversarial proceedings or litigation in other jurisdictions seeking to challenge the validity of our intellectual property rights, claiming that we have misappropriated the trade secrets of others, or claiming that our technologies, products or activities infringe the intellectual property rights of others.

There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, post grant review, inter partes review and reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

We are aware of patents owned by third parties, including potential competitors, that are directed to compositions comprising a chemically modified opioid, such as oxycodone, which decreases the potential of the opioid to be abused or cause overdose and related methods of use. Third parties, including potential competitors, may assert infringement claims against us based on existing patents or patents that may be granted in the future including, perhaps, the aforementioned patents, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us.

Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or to enable the commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In such an event, we would be unable to further practice our technologies or develop and commercialize any of our product candidates at issue, which could harm our business and financial condition significantly.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates, if approved. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee time and resources from our business. Third parties making such claims may have the ability to dedicate substantially greater resources to these legal actions than us or our licensors or collaborators can. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Patent litigation and other proceedings may also absorb significant management time. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. During the course of any patent or other intellectual property litigation or other proceeding, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings or developments and if securities analysts or investors regard these announcements as negative, the perceived value of our product candidates or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, ability to compete in the marketplace, financial condition, results of operations and growth prospects.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights or other intellectual property, or those of our licensors. To counter infringement, misappropriation, unauthorized use or other violations, we may be required to file legal claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel.

There can be no assurances that we will be successful with respect to any litigation matters which may arise in the ordinary course of our business. Such a failure may have a material impact on our business, results of operations and financial condition in the future.

We may not be able to prevent, alone or with any future licensors, infringement, misappropriation or other violations of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims,

a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement, misappropriation or other intellectual property litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

The expiration or loss of patent protection may adversely affect our future revenues and operating earnings.

We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing and sale of our product candidates. In particular, patent protection is important in the development and eventual commercialization of our product candidates. Patents covering our product candidates normally provide market exclusivity, which is important in order to improve the probability that our product candidates are able to become profitable.

Certain of our patents relating to PF614 and the use of nafamostat for treating respiratory diseases will expire in less than ten years. While we are seeking additional patent coverage which may protect the technology underlying these patents, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan. In the United States, the normal statutory term of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection of our product candidates, we may be open to competition from generic versions of such methods and compositions.

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term, our business may be harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension, or PTE, under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we request. Even if we are able to obtain an extension, the patent term may still expire before or shortly after we receive FDA marketing approval. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets.

Additionally, the requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and our patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of us or our licensors' patents, requiring us or our licensees or any future licensors to engage in complex, lengthy and costly litigation or other proceedings. In addition, certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In certain jurisdictions, such as in the Russian Federation, our patents may not be honored since patent holders in the United States may be deemed "unfriendly countries". In those countries and jurisdictions, we and our licensees or any future licensors may have limited remedies if patents are infringed or if we or our licensees or any future licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, we and our licensees' or any future licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We may be subject to claims that we or our employees, consultants, contractors or advisors have infringed, misappropriated or otherwise violated the intellectual property of a third party, or claiming ownership of what we regard as our own intellectual property.

Many of the contributors to our intellectual property, including patents and applications, were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the intellectual property and other proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees have used or disclosed such intellectual property or other proprietary information. Litigation may be necessary to defend against these claims.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. For example, we have not obtained assignments for certain patent applications relating to abuse-resistant amphetamines. To the extent that we fail to obtain such assignments, such assignments do not contain a self-executing assignment of intellectual property rights or such assignments are breached, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed and if we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, in seeking to develop and maintain a competitive position. Because we expect to rely on third parties to manufacture our product candidates and we expect to collaborate with third parties on the development of our product candidates, we must, at times, share trade secrets with them. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, corporate collaborators, outside scientific collaborators, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective.

Since our inception, we have sought to contract with manufacturers to supply commercial quantities of pharmaceutical formulations and products. As a result, we have disclosed, under confidentiality agreements, various aspects of our technology with potential manufacturers and suppliers. We believe that these disclosures, while necessary for our business, may have resulted and may result in the attempt by potential manufacturers and suppliers to improperly assert ownership claims to our technology in an attempt to gain an advantage in negotiating manufacturing and supplier rights.

We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If we fail to prevent material disclosure of the know-how, trade secrets and other intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. Even if we are able to adequately protect our trade secrets and proprietary information, our trade secrets could otherwise become known or could be independently discovered by our competitors. For example, we are aware that certain of our former employees founded Elysium Therapeutics, which appears to be developing orally administered abuse deterrent opioids. Additionally, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, in the absence of patent protection, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us.

We may not be able to prevent misappropriation of our intellectual property, trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in the patents and intellectual property that we own or that we may own or license in the future. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own; our licensors may face similar obstacles. In addition, we have not updated the records in the patent offices to reflect our ownership of our patent filings obtained as a result of the merger with Signature, including patent filings relating to PF614 and other technologies. Failure to update such ownership may result in an innocent purchaser potentially acquiring rights in such patents that are adverse to our interests. Furthermore, as noted above, we have not obtained assignments for certain patent applications relating to abuse-resistant amphetamines. We could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against any claims challenging inventorship or ownership. If we fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, results of operations and financial condition.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our product candidates.

To the extent undertaken, we cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is or may be relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the

priority date. In addition, certain United States patent applications can remain confidential until patents issue. Therefore, patent applications covering our products could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. Disputes may arise between us and any of these counterparties regarding intellectual property rights that are subject to such agreements, including, but not limited to:

- the scope of rights granted under the agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- our right to sublicense patent and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign our license; and
- the effects of termination.

The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail to comply with our obligations under any agreements, we may be required to pay damages and could lose intellectual property rights that are necessary or useful for developing and protecting our product candidates.

We have acquired all intellectual property rights from Signature and Mucokinetica, with the exception of our pending application directed to the use of orally administered nafamostat to treat coronaviruses. Any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any such material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology, or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology.

Intellectual property rights do not necessarily address all potential threats to our business.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business. The following examples are illustrative:

- others may be able to make formulations that are similar to our product candidates or other formulations but that are not covered by the claims of our patent rights;
- the patents of third parties may have an adverse effect on our business;
- we or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own;
- we or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we may own or that we exclusively license in the future may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

The validity, scope and enforceability of any patents listed in the Orange Book that cover our product candidates can be challenged by third parties.

If one of our product candidates is approved by the FDA, one or more third parties may challenge the current patents, or patents that may issue in the future, within our portfolio which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement. For example, if a third party submits an application under Section 505(b)(2) or an abbreviated new drug application, or ANDA, for a generic drug containing any of our product candidates, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the Orange Book with respect to our NDA for the applicable approved drug candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved drug candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval.

Moreover, a third party may challenge the current patents, or patents that may be issued in the future, within our portfolio which could result in the invalidation of some or all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products, we will not be entitled to the 30-month stay of FDA approval upon the filing of an ANDA for a generic drug containing any of our product candidates, and relies in whole or in part on studies conducted by or for us. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our product candidates.

If we do not obtain protection under the Hatch-Waxman Amendments by obtaining data exclusivity, our business may be harmed.

Our commercial success will largely depend on our ability to obtain and market exclusivity in the United States and other countries with respect to our product candidates. Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, certain of our product candidates may be eligible for marketing exclusivity.

The FDC Act provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA or Section 505(b)(2) NDA for a new chemical entity, or NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. If market exclusivity is granted for an NCE, during the exclusivity period, the FDA may not accept for review or approve an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, which we refer to as the Orange Book, with the FDA by the innovator NDA holder.

The FDC Act also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, dosage forms or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and prohibits the FDA from approving an ANDA, or a Section 505(b)(2) NDA submitted by another company with overlapping conditions associated with the new clinical investigations for the three-year period. Three-year exclusivity does not prohibit the FDA from approving ANDAs for drugs containing the original conditions of use. Five-year and three-year exclusivity will not delay the submission or approval of an NDA for the same drug. However, an applicant submitting an NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

If we are unable to obtain such marketing exclusivity for our product candidates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our approval to obtain approval of competing products and launch their product earlier than might otherwise be the case.

Cyber-attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, CROs, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations.

We, our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of us, our collaborators', CROs', third-party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, business email compromise attacks or other cyber-attacks. Any cyber-attack, data breach or destruction or loss of data could result in a violation of applicable United States and international privacy, data protection and other laws and subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed, which could have a material adverse effect on our business and prospects. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

Risks Related to the Ownership of Common Stock and Financial Reporting

Raising additional capital could cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. For example, the subsequent conversion of the 2021 Notes sold on September 24, 2021 and November 5, 2021 into common stock would result in dilution to stockholders.

To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, our stockholders' ownership interest may be diluted. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates. Further, we may incur additional dilution from repayment of the 2021 Notes in common stock or resetting the conversion price of the 2021 Notes if we issue equity at a price below the conversion price of the 2021 Notes. Also, we will receive reduced proceeds if the exercise price of the warrants granted in connection with the 2021 Notes is reduced.

If we raise additional capital through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital when needed, we may be required to grant to third parties rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves.

In addition, any issuances of common stock pursuant to the GEM Agreement would result in dilution of the ownership interest of our stockholders. Any such issuances may also have a negative impact on the market price of our common stock because of the discount at issuance. See "*—We require substantial additional funding. If we are unable raise capital when needed, we could be forced to delay, reduce or terminate our product discovery and development programs or commercialization efforts*" for description of risks related to additional funding.

Our internal controls over financial reporting currently do not meet all of the standards contemplated by Section 404 of Sarbanes-Oxley Act, and failure to achieve and maintain effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could impair our ability to produce timely and accurate financial statements or comply with applicable regulations and have a material adverse effect on our business.

We previously operated as a private company. In connection with the preparation of our consolidated financial statements for the years ended December 31, 2021 and 2020, we concluded that there were material weaknesses in our internal controls over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal controls over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses identified are insufficient internal controls because of inadequate technical accounting expertise and inappropriate level of supervision and review due to the limited number of accounting personnel. While we have taken steps to remediate the material weaknesses in our internal controls over financial reporting, including hiring a Chief Financial Officer in February 2021, we may not be successful in remediating such weaknesses.

Following the Merger, our management has significant requirements for enhanced financial reporting and internal controls as a public company. The process of designing and implementing effective internal controls is a continuous effort that will require us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. If we are unable to establish or maintain appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations on a timely basis or result in material misstatements in our consolidated financial statements, which could harm our operating results. In addition, we are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. Testing and maintaining internal controls may divert management's attention from other matters that are important to our business. Our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting on an annual basis. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are not able to complete an initial assessment of our internal controls and otherwise implement the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner or with adequate compliance, our independent registered public accounting firm may not be able to certify as to the adequacy of our internal controls over financial reporting.

Matters impacting our internal controls may cause us to be unable to report our financial information on a timely basis and thereby subject us to adverse regulatory consequences, including sanctions by the Securities and Exchange Commission, or SEC, or violations of applicable stock exchange listing rules, which may result in a breach of the covenants under existing or future financing arrangements. There also could be a negative reaction in the financial markets due to a loss of investor confidence in us and the reliability of our financial statements. Confidence in the reliability of our financial statements also could suffer if we or our independent registered public accounting firm continue to report a material weakness in our internal controls over financial reporting. This could materially adversely affect us and lead to a decline in the market price of our common stock.

Risks Related to Our Securities and to Being a Public Company

We are an emerging growth company and a smaller reporting company within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to "emerging growth companies" or "smaller reporting companies," this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies.

We are an "emerging growth company" within the meaning of the Securities Act, as modified by the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700 million as of the end of any second quarter of a fiscal year, in which case we would no longer be an emerging growth company as of the last day of such fiscal year. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until

private companies (that is, those that have not had a registration statement under the Securities Act declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company that is not an emerging growth company or is an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common stock held by non-affiliates is greater than or equal to $250 million as of the end of that fiscal year's second fiscal quarter, and (ii) our annual revenues are greater than or equal to $100 million during the last completed fiscal year and the market value of our common stock held by non-affiliates exceeds $700 million as of the end of that fiscal year's second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

The amount of our future losses is uncertain and our quarterly and annual operating results may fluctuate significantly or fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry,
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts, including as a result of COVID-19;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;

- our ability to obtain marketing approval for our product candidates and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the changing and volatile U.S. and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results or revenue fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide, if any.

If the Nasdaq delists our common stock and/or our Public Warrants do not continue to trade on the OTC Pink Open Market, this could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

If Nasdaq delists our common stock and/or our Public Warrants do not continue to trade on the OTC Pink Open Market, as applicable, from trading on their exchanges for failure to meet the listing standards, our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in such securities to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future, including our inability to obtain financing under the GEM Agreement.

Warrants for shares of our common stock, if exercised, will increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

There are Public Warrants currently exercisable for an aggregate of approximately 10,000,000 shares of our common stock at an exercise price of $11.50 per share. In addition, there are private warrants exercisable for an aggregate of 11,090,873 shares of our common stock at a weighted-average exercise price of $10.36 per share. To the extent such warrants are exercised, additional shares of our common stock will be issued, which will result in dilution to the holders of shares of our common stock and increase the number of shares of common stock eligible for resale in the public market. Sales of substantial numbers of such shares of common stock in the public market or the fact that such warrants may be exercised could adversely affect the market price of our common stock.

Substantial blocks of our total outstanding shares may be sold into the market. If there are substantial sales of shares of our common stock, the price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of shares of our common stock by our directors, executive officers, or significant stockholders, if there is a large number of shares of our common stock available for sale, or if there is the perception that these sales could occur. Immediately after the Merger, a significant portion of our shares of common stock or warrants exercisable for our shares of common stock were held by persons who had been affiliated with LACQ prior to the Merger but did not remain so with respect to us after the Merger. In addition, we have registered shares of common stock that we may issue under our 2021 Omnibus Incentive Plan. Shares held by our directors, executive officers and other affiliates are subject to restrictions on resale under the Securities Act and may be subject to various vesting agreements.

Certain of our initial stockholders have agreed, subject to certain exceptions, not to transfer, pledge, assign, sell or otherwise dispose of any of our common stock held by them immediately after the Merger until the earlier to occur of (a) one year after the Merger and (b) the date on which we complete a liquidation, merger, share exchange or other similar transaction after closing that results in all of our stockholders having the right to exchange their common shares for cash, securities or other property. However, if the closing price of our common shares equals or exceeds $12.00 per share (as adjusted for share splits, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within any 30-trading day period commencing at least 150 days after the Merger, the shares of those initial stockholders will be released from the lock-up.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of such shares intend to sell their shares.

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our 2021 Omnibus Incentive Plan and to repay interest or principal on the 2021 Notes or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors, and consultants under our 2021 Omnibus Incentive Plan. We may use our common stock to make repayment of some or all of the principal and interest on the 2021 Notes. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

Trading on the OTC Pink Open Market is volatile and sporadic, which could depress the market price of the Public Warrants and make it difficult for the Public Warrant holders to resell their Public Warrants.

The Public Warrants are quoted on the OTC Pink Open Market. Trading in securities quoted on the OTC Pink Open Market is often thin and characterized by wide fluctuations in trading prices, due to many factors, some of which may have little to do with our operations or business prospects. This volatility could depress the market price of the Public Warrants for reasons unrelated to operating performance. Moreover, the OTC Pink Open Market is not a stock exchange, and trading of securities on the OTC Pink Open Market is often more sporadic than the trading of securities listed on Nasdaq. These factors may result in investors having difficulty reselling any Public Warrants.

While LACQ determined that the Public Warrants should be classified as equity and its private warrants will be treated as equity on a pro forma basis, due to the uncertainty with respect to classification of warrants issued by SPACs as equity or indebtedness, there can be no assurance that future guidance might not require us to change this position and restate our financial statements and have other adverse consequences.

While LACQ's financial statements were restated to classify its private warrants as liabilities, we have determined that it is appropriate to continue to classify the Public Warrants as equity. We reviewed the terms of the warrant agreement related to the Public Warrants and concluded that they do not include any provision requiring the Public Warrants to be classified as liabilities. In this respect, it should be noted that the warrant agreement included a provision that in the event of a tender or exchange offer made to and accepted by holders of more than 50% of the outstanding shares of a single class of common shares, all holders of the warrants could be entitled to receive cash for their warrants (the "*tender offer provision*"). This tender offer provision was similar to one of the examples referred to in the SEC Statement as a basis for concluding that warrants issued by a SPAC should be classified as liabilities and not equity. LACQ concluded that, while the SEC Statement did not expressly refer to a multi-class structure (such as a structure where a SPAC had two classes of common stock), the SEC Statement with respect to a tender offer provision in a warrant agreement applied to a multi-class structure (such as a Class A and Class B structure) and not a single class structure like the Public Warrants. Certain other SPACs, including those with single class structures, have taken different approaches in their public filings with the SEC and have classified similar warrants as liabilities.

LACQ classified its private warrants as liabilities because they provided for potential changes to the settlement amounts dependent upon the characteristics of the holder of the warrant (i.e., certain rights differ if the warrants are held by the original holder and its permitted transferees or by a subsequent transferee). LACQ entered into agreements with the holders of its private warrants under which each holder exchanged its private warrants for warrants on the same terms as the private warrants, except that they are non-transferable except to certain permitted transferees. LACQ believed that as a result of the exchange, the private warrants would be appropriately classified as equity and not liabilities subsequent to the date of such agreements.

The accounting treatment of warrants issued in SPAC transactions is subject to substantial uncertainty and there can be no assurance that future guidance might not require us to change LACQ's position and restate our financial statements or treat private warrants as liabilities, which could have a material adverse effect on us.

Our common stock could be delisted from Nasdaq and may become subject to "penny stock" rules, which could damage our reputation and the ability of investors to sell their shares.

There can be no assurance that our common stock will maintain our listing on Nasdaq which could have a material adverse effect on us. Upon any delisting, our common stock could become subject to the regulations of the SEC relating to the market for penny stocks. Penny stocks are securities with a price of less than $5.00 per share unless (i) the securities are traded on a "recognized" national exchange or (ii) the issuer has Net Tangible Assets less than $2,000,000 (if the issuer has been in continuous operation for at least three years) or $5,000,000 (if in continuous operation for less than three years), or with average annual revenues of less than $6,000,000 for the last three years.

The procedures applicable to penny stocks requires a broker-dealer to (i) obtain from the investor information concerning his financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of stockholders to sell their common stock in the secondary market.

Our directors and executive officers own a significant percentage of our common stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2021, our executive officers and directors beneficially owned approximately 52.0% of our common stock. These stockholders, acting together, may be able to control matters requiring stockholder approval. For example, they may be able to control elections of directors, changes to equity incentive plans, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transactions. This concentration of ownership control may delay, discourage or prevent a change of control, including unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders,

entrench our management and board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us that other stockholders may desire. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our principal executive office is located at 7946 Ivanhoe Ave., Suite 201 in La Jolla, California, where we lease a total of 850 square feet of office space that we use for our administrative activities. The lease expires in October 2022. All other development activities are undertaken at contract research organizations.

We believe that all of our facilities are in good condition and are well maintained and that our current arrangements will be sufficient to meet our needs for the foreseeable future, and that, should it be needed, suitable additional space will be available to accommodate any such expansion of our operations.

Item 3. Legal Proceedings

From time to time, we could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. Periodically, we review the status of significant matters, if any exist, and assesses its potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount can be estimated, we accrue a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict. Because of such uncertainties, accruals are based on the best information available at the time. As additional information becomes available, we reassess the potential liability related to pending claims and litigation.

DelMorgan Group, LLC et al. v. Ensysce Biosciences, Inc., et al., Los Angeles County Superior Court, Case Number 21 STCV25585

In July 2021, following the Merger, the Company's former financial advisor, Del Morgan Group, LLC and Globalist Capital, LLC (together, "*Plaintiffs*") filed an action against the Company and its Chief Executive Officer (together, "*Defendants*") alleging that the common stock and warrants (together, "*Securities*") issued to Plaintiffs in satisfaction of its advisory fee should have been registered and the Securities immediately tradeable. The Plaintiffs asserted various causes of action in furtherance of their claims. The Plaintiffs were seeking registered and freely tradeable Securities and damages arising from their inability to trade the Securities, which Plaintiffs asserted are in the millions of dollars. The Defendants believed there were meritorious defenses to the Plaintiffs claims, and possible counterclaims.

On August 3, 2021, the Plaintiffs and Defendants entered into a Settlement Agreement and Mutual General Release whereby Plaintiffs would have their common stock, and the common stock underlying their warrants registered on the Company's Form S-1 Registration Statement. In addition, the warrants would be modified to allow for cashless exercise and to reduce the exercise price from $11.50/share to $10.00/share. In consideration for this, both Parties agreed to release the other from any past, present or future claims. In addition, the Plaintiffs agreed to immediately stay the proceedings and inform the Superior Court of a conditional settlement and to dismiss the lawsuit with prejudice five days following the effectiveness of the Form S-1 Registration Statement. On October 6, 2021, the Superior Court dismissed with prejudice the case filed on July 12, 2021 by the Plaintiffs, following effectiveness of the Resale Registration Statement filed on August 9, 2021 and amended on September 22, 2021.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases Of Equity Securities

Market Price and Ticker Symbol

Our common stock is currently listed on the Nasdaq Stock Market under the symbol "ENSC." Our Public Warrants are currently listed on the OTC Pink Open Market under the symbol "ENSCW."

The closing price of our common stock and Public Warrants on March 25, 2022, was $1.13 and $0.15, respectively.

Holders

As of March 25, 2022, there were approximately 161 holders of record of our common stock, one holder of record of the Public Warrants, eight holders of record of the LACQ private warrants, one holder of the GEM Warrants, and three holders of record of 2021 Notes warrants.

Such numbers do not include beneficial owners holding our securities through nominee names.

Dividends

We have not paid any cash dividends on our common stock to date. We may retain future earnings, if any, for future operations, expansion and debt repayment and has no current plans to pay cash dividends for the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of the Board and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that the Board may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. We do not anticipate declaring any cash dividends to holders of our common stock in the foreseeable future.

Recent Sales of Unregistered Securities and Use of Proceeds

We entered into an Investor Relations Consulting Agreement with MZHCI, LLC on December 20, 2021, through which we receive ongoing stock market support services and other consulting services. Pursuant to that agreement, we pay a monthly fee and we issued 50,000 unregistered shares of our common stock in February 2022. The issuance of our shares was exempt from registration under Section 4(a)(2) of the Securities Act as it was a private transaction between MZHCI, LLC and us. We received no proceeds in connection with our issuance of those 50,000 shares.

On September 24, 2021, we entered into the SPA for an aggregate financing of $15.0 million with institutional investors. A first closing under the SPA for $5 million occurred on September 24, 2021 and a second closing under the SPA occurred on November 5, 2021. At the first closing, the Company issued to the investors (i) senior secured convertible promissory notes in the aggregate principal amount of $5.3 million for an aggregate purchase price of $5.0 million and (ii) warrants to purchase 361,158 shares of the Company's common stock in the aggregate at an exercise price of $7.63 per share. At the second closing, the Company issued to the institutional investors referenced above, (i) senior secured convertible promissory notes in the aggregate principal amount of $10.6 million for an aggregate purchase price of $10.0 million and (ii) warrants to purchase 722,317 shares of the common stock in the aggregate at an exercise price of $7.63 per share. The proceeds will go toward working capital purposes subject to certain customary restrictions. See, "*Liquidity and Capital Resources*" for a detailed description of the 2021 Notes.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

Ensysce is a clinical stage pharmaceutical company seeking to develop innovative solutions for severe pain relief while reducing the fear of and the potential for addiction, opioid misuse, abuse and overdose. We have also incorporated a 79.2%-owned subsidiary, Covistat, a clinical stage pharmaceutical company that is developing a compound utilized in our overdose protection program for the treatment of COVID-19. Our lead product candidate, PF614, is an extended release TAAP prodrug of oxycodone. TAAP modification of prescription drugs removed the ability to crush, chew or manipulate and inject to achieve the medication more quickly than by swallowing. MPAR™ adds a layer of overdose protection to each TAAP product.

Since our inception in 2003, we devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, discovering product candidates and securing related intellectual property rights and conducting research and development activities for our product candidates. We do not have any products approved for sale and we have not generated any revenue from product sales. We may never be able to develop or commercialize a marketable product.

Our lead product candidate, PF614, is in Phase 1b clinical development, PF614-MPAR™ is in Phase 1 clinical development and nafamostat is proceeding towards Phase 2 clinical development. Our other product candidates and our research initiatives are in preclinical or earlier stages of development. Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. We have not yet successfully completed any pivotal clinical trials, nor have we obtained any regulatory approvals, manufactured a commercial-scale drug, or conducted sales and marketing activities.

We expect to continue to incur net losses for the foreseeable future, and we expect our clinical development expenses, and general and administrative expenses to continue to increase. We have incurred significant operating losses since inception. Our net loss was $29.1 million for the year ended December 31, 2021 and as of December 31, 2021, we had an accumulated deficit of $85.8 million. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing development activities, particularly if and as we:

- continue preclinical studies and continues existing and initiates new clinical trials for PF614, PF614-MPAR™ and nafamostat, our lead product candidates being tested for chronic pain and infectious disease;
- advance the development of our product candidate pipeline of other product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support our clinical operations;
- seek regulatory approval for any product candidates that successfully complete clinical trials;
- undertake any pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval;
- expand our infrastructure and facilities to accommodate our growing employee base; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and our transition to operating as a public company.

We expect to incur additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other expenses that we did not incur as a private company. We may never become profitable.

We require substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of private and public equity offerings, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. To the extent that we raise additional capital through the sale of private or public equity or convertible debt securities, existing ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our equity holders.

Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations or other strategic transactions with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

We have generated limited revenues and have incurred significant operating losses since our inception, and as of December 31, 2021, have an accumulated deficit of $85.8 million. In addition, we expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern. We believe that our available resources and existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through the third quarter of 2022. We based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "— *Liquidity and Capital Resources*." Our future viability beyond the twelve months is dependent on our ability to raise additional capital to finance our operations.

We expect to incur substantial expenses in the foreseeable future for the development and potential commercialization of our product candidates and ongoing internal research and development programs. At this time, we cannot reasonably estimate the nature, timing or aggregate amount of costs for our development, potential commercialization, and internal research and development programs. However, in order to complete our current and future preclinical studies and clinical trials, and to complete the process of obtaining regulatory approval for our product candidates, as well as to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we may require substantial additional funding in the future.

COVID-19 Pandemic Business Update

In March 2020, the World Health Organization declared COVID-19 a global pandemic. To date, our financial condition and operations have not been significantly impacted by the ongoing COVID-19 pandemic. However, we cannot at this time predict the specific extent, duration, or full impact that the ongoing COVID-19 pandemic will have on our financial condition and operations, including ongoing and planned clinical trials and other operations required to support those clinical trials and research and development activities to advance our pipeline. The impact of the ongoing COVID-19 pandemic on our financial performance will depend on future developments, including the duration and spread of the pandemic and related governmental advisories and restrictions. These developments and the impact of the ongoing COVID-19 pandemic on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, our results may be materially adversely affected.

We are continuing to evaluate the impact of the ongoing COVID-19 pandemic on our business and continue to take proactive measures to protect the health and safety of our employees, as well as to maintain business continuity. We believe that the current measures we have implemented with respect to the ongoing COVID-19 pandemic are appropriate, reflecting both regulatory and public health guidance, to maintain business continuity. We will continue to closely monitor and seek to comply with guidance from governmental authorities and adjust our activities as appropriate.

Convertible Promissory Notes

On September 24, 2021, we entered into the SPA for an aggregate financing of $15.0 million with institutional investors. A first closing under the SPA occurred on September 24, 2021 and a second closing under the SPA occurred on November 5, 2021. At the first closing, the Company issued to the investors (i) senior secured convertible promissory notes in the aggregate principal amount of $5.3 million for an aggregate purchase price of $5.0 million (collectively, the "*First Closing Notes*") and (ii) warrants to purchase 361,158 shares of the Company's common stock in the aggregate at an exercise price of $7.63 per share. At the second closing, the Company issued to the institutional investors referenced above, (i) senior secured convertible promissory notes in the aggregate principal amount of $10.6 million (collectively, the "*Second Closing Notes*", together with the First Closing Notes, the "*2021 Notes*") for an aggregate purchase price of $10.0 million and (ii) warrants to purchase 722,317 shares of the Company's common stock in the aggregate at an exercise price of $7.63 per share.

The Notes, subject to an original issue discount of six percent (6%), have a term of twenty-one months from the date of issuance and accrue interest at the rate of 5.0% per annum. The Notes are convertible into common stock, at a per share conversion price equal to $5.87, a 30% premium to the average price of the common stock for the three trading days prior to the first closing under the SPA.

Under the 2021 Notes, on the first day of each month, we are obligated to redeem (i) an amount equal to ninety-two percent (92%) of the average of the three lowest VWAPs (as defined in the SPA) in the ten trading days prior to such date or (ii) an amount in cash with a premium of eight percent of the one eighteenth ($1/18^{th}$) of the original principal amount under the applicable Note, plus accrued but unpaid interest, liquidated damages and any other amounts then owing to the holder of such Note. Our redemption obligation commenced on January 1, 2022 for the First Closing Notes and February 1, 2022 for the Second Closing Notes.

The Company may elect to pay all or part of the redemption amount in the conversion of the 2021 Notes into shares of common stock based on a conversion price equal to the lesser of (i) the conversion price and (ii) 92% of the average of the three lowest VWAPs (as defined in the SPA) during the ten (10) consecutive trading days ending on the trading day that is immediately prior to the applicable redemption date, but in no event may we pay the redemption amount in conversion shares of common stock unless the conversion price is at least equal to $0.78 and certain equity conditions are satisfied.

On December 27, 2021, the Company issued a Letter of Agreement amending the Securities Purchase Agreement to allow for conversion of the outstanding notes at an exercise price of $4.50 per share of the Company's common stock for fourteen trading days, commencing December 28, 2021 and ending January 14, 2022. Following this period, the initial conversion price of $5.87 was restored.

The warrants have an exercise price of $7.63, a 30% premium to the conversion price (and subject to downward adjustments based on certain issuances of the Company's common stock) and are exercisable for five years following issuance. The Company issued, to the purchasers' signatory to the SPA, warrants to purchase up to a number of shares of common stock equal to forty percent (40%) of the shares of common stock issuable to each purchaser under the SPA upon conversion of the Note such purchaser holds on each of the first and second closing date under the SPA.

We registered with the Securities and Exchange Commission the resale of the shares of common stock issuable upon conversion of the Notes as well as the shares of common stock issuable upon the exercise of the warrants pursuant to a Registration Rights Agreement, dated September 24, 2021, by and among the Company and the purchasers' signatory to the SPA.

The 2021 Notes contain certain covenants, and events of default and triggering events, respectively, which would require repayment of the obligations outstanding pursuant to such instruments. Our obligations pursuant to the 2021 Notes are (i) secured by all assets of the Company and all subsidiaries of the Company pursuant to the Security Agreement and Patent Security Agreement, each dated September 24, 2021, by and among the Company, the subsidiaries of the Company and the holders of the 2021 Notes and (ii) guaranteed jointly and severally by the subsidiaries of the Company pursuant to the Subsidiary Guarantee, dated September 24, 2021, by and among the Company, the subsidiaries of the Company and the purchasers signatory to the SPA.

Business Combination Transaction

On June 30, 2021, the Merger with LACQ was consummated and we became a public company. We received net proceeds of approximately $7.8 million at the closing and we continue to operate under our management team, led by our Chief Executive Officer Lynn Kirkpatrick. On July 2, 2021, the combined company's common stock began trading on Nasdaq under the ticker symbol "ENSC".

Components of Our Operating Results

Revenue

We have generated limited revenue since our inception and we do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts are successful and we commercialize our products, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales, as well as upfront, milestone and royalty payments from such collaboration or license agreements, or a combination thereof.

We have received funding under federal grants from the NIH through NIDA. In September 2018, we were awarded the MPAR Grant. In September 2019, we were awarded a second research and development grant, the OUD Grant. Grant funds are awarded annually through a Notice of Award which contains certain terms and conditions including, but not limited to, complying with the grant program legislation, regulation and policy requirements, complying with conditions on expenditures of funds with respect to other applicable statutory requirements such as the federal appropriations acts, periodic reporting requirements, and budget requirements.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for research activities, including drug discovery efforts and the development of our product candidates. We expense research and development costs as incurred, which include:

- expenses incurred to conduct the necessary preclinical studies and clinical trials required to obtain regulatory approval;
- expenses incurred under agreements with CROs that are primarily engaged in the oversight and conduct of our drug discovery efforts and preclinical studies, clinical trials and CMOs that are primarily engaged to provide preclinical and clinical drug substance and product for our research and development programs;
- other costs related to acquiring and manufacturing materials in connection with our drug discovery efforts and preclinical studies and clinical trial materials, including manufacturing validation batches, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- payments made in cash or equity securities under third-party licensing, acquisition and option agreements;
- employee-related expenses, including salaries and benefits, travel and stock-based compensation expense for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements; and
- allocated facilities-related costs, depreciation and other expenses, which include rent and utilities.

We recognize external development costs as incurred. Any advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are expensed as the related goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered. We estimate and accrue for the value of goods and services received from CROs and other third parties each reporting period based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs.

We do not track our research and development expenses on a program-by-program basis. Our direct external research and development expenses consist primarily of external costs, such as fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct our research and discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track our costs by program and cannot state precisely the total costs incurred for each of our clinical and preclinical programs on a project-by-project basis.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially over the next several years as we continue our existing, and commences additional, planned clinical trials for PF614, PF614-MPAR™ and nafamostat, as well as conduct other preclinical and clinical development, including submitting regulatory filings for our other product candidates. We also expect our discovery research efforts and our related personnel costs to increase and, as a result, we expect our research and development expenses, including costs associated with stock-based compensation, to increase above historical levels. In addition, we may incur additional expenses related to milestone and royalty payments payable to third parties with whom we may enter into license, acquisition and option agreements to acquire the rights to future product candidates.

At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. The successful development and commercialization of our product candidates are highly uncertain. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of the following:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- establishing an appropriate safety and efficacy profile with IND enabling studies;
- successful patient enrollment in and the initiation and completion of clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;

- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses, including salaries and related benefits, travel and stock-based compensation for personnel in executive, business development, finance, human resources, legal, information technology, and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as insurance costs and professional fees for legal, patent, consulting, investor and public relations, accounting and audit services. We expense general and administrative costs as incurred.

We anticipate that our general and administrative expenses, excluding non-cash expenses to recognize the fair value of warrants issued with the share subscription facility, will increase in the future as we increase our headcount to support the continued development of our product candidates. We also anticipate that we will incur significantly increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other employee-related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of that product candidate.

Other Income (Expense)

Derivative Liabilities

Between 2018 and 2021, we entered into a series of notes that were determined to have embedded derivative instruments in the form of a contingent put option. The notes were recognized at the value of proceeds received after allocating issuance proceeds to the bifurcated contingent put option. The notes were subsequently measured at amortized cost using the effective interest method to accrete interest over their term to bring the notes' initial carrying value to their principal balance at maturity. The bifurcated put option was initially measured at fair value and subsequently measured at fair value with changes in fair value recognized as a component of other expenses in the consolidated statements of operations. These notes and associated derivatives were settled during 2021.

Convertible Notes

We elected the fair value option to account for the 2021 Notes as we believe the fair value option provides users of the financial statements with greater ability to estimate the outcome of future events as facts and circumstances change, particularly with respect to changes in the fair value of the common stock underlying the conversion option. We use a Monte Carlo analysis to estimate the fair value of the conversion feature of the notes, which relies on unobservable Level 3 inputs. We use a discounted cash flow model to estimate the fair value of the debt component of the 2021 Notes. Changes in the fair value of the notes are recognized through earnings for each reporting period. The impact to the consolidated statement of operations related to these 2021 Notes is reflected in the following lines: Change in fair value of convertible notes and issuance costs for convertible notes. Such issuance costs include investment banking and legal fees as well as original issue discounts on the 2021 Notes.

Liability Classified Warrants

The warrants issued with the 2021 Notes were liability classified due to certain cash settlement features. We use a Black-Scholes option pricing model to estimate the fair value of the warrants. Changes in the fair value of the warrants are recognized through earnings for each reporting period.

Interest Expense

Interest expense consists of interest accrued on our convertible and other promissory notes and the amortization of debt discounts in our convertible promissory notes that were settled on June 30, 2021, in conjunction with the Merger. Interest expense related to the 2021 Notes is included in the estimate of fair value of the convertible notes.

Provision for Income Taxes

We have not recorded any significant amounts related to income tax expense, we have not recognized any reserves related to uncertain tax positions, nor have we recorded any income tax benefits for the majority of our net losses we have incurred to date or for our research and development tax credits.

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or our tax returns. Deferred tax assets and liabilities are determined based on difference between the financial statement carrying amounts and tax bases of existing assets and liabilities and for loss and credit carryforwards, which are measured using the enacted tax rates and laws in effect in the years in which the differences are expected to reverse. The realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of December 31, 2021 and 2020, we continue to maintain a full valuation allowance against all of our deferred tax assets based on our evaluation of all available evidence.

We file income tax returns in the United States federal tax jurisdiction and state jurisdictions and may become subject to income tax audit and adjustments by related tax authorities. Our tax return period for United States federal income taxes for the tax years since 2017 remain open to examination under the statute of limitations by the Internal Revenue Service and state jurisdictions. We record reserves for potential tax payments to various tax authorities related to uncertain tax positions, if any. The nature of uncertain tax positions is subject to significant judgment by management and subject to change, which may be substantial. These reserves are based on a determination of whether and how much a tax benefit taken by us in our tax filings or whether our position is more likely than not to be realized following the resolution of any potential contingencies related to the tax benefit. We develop our assessment of uncertain tax positions, and the associated cumulative probabilities, using internal expertise and assistance from third-party experts. As additional information becomes available, estimates are revised and refined. Differences between estimates and final settlement may occur resulting in additional tax expense. Potential interest and penalties associated with such uncertain tax positions is recorded as a component of our provision for income taxes. To date, no amounts are being presented as an uncertain tax position.

Results of Operations

Comparison of the Years ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020:

	Year Ended December 31,		
	2021	2020	Change
Federal grants	$ 3,531,199	$ 3,931,209	$ (400,010)
Operating expenses:			
Research and development	$ 4,690,082	$ 4,389,579	$ 300,503
General and administrative	18,711,548	1,154,917	17,556,631
Total operating expenses	23,401,630	5,544,496	17,857,134
Loss from operations	(19,870,431)	(1,613,287)	(18,257,144)
Other income (expense):			
Change in fair value of derivative liabilities	673,314	2,447,908	(1,774,594)
Issuance costs for convertible notes	(1,920,158)	-	(1,920,158)
Change in fair value of convertible notes	(2,993,060)	-	(2,993,060)
Issuance of liability classified warrants	(1,865,403)	-	(1,865,403)
Change in fair value of liability classified warrants	(1,438,186)	-	(1,438,186)
Interest expense	(1,295,307)	(995,496)	(299,811)
Other income and expense, net	(436,670)	-	(436,670)
Total other income (expense), net	(9,275,470)	1,452,412	(10,727,882)
Net loss	$ (29,145,901)	$ (160,875)	$ (28,985,026)
Net loss attributable to noncontrolling interests	(62,190)	(217,645)	155,455
Deemed dividend related to warrants down round provision	(803,140)	-	(803,140)
Net income (loss) attributable to common stockholders	$ (29,886,851)	$ 56,770	$ (29,943,621)

Federal Grants

Revenue from federal grants totaled $3.5 million for the year ended December 31, 2021, compared to $3.9 million for the year ended December 31, 2020. The decrease related to two grants from the NIH through NIDA. Revenue decreased $0.4 million during the year ended December 31, 2021, due to the timing of research activities eligible for funding under the grants under the MPAR™ grant awarded in September 2018. We expect funding from federal grants in the future to approximate current levels.

Research and Development Expenses

Research and development expenses were $4.7 million for the year ended December 31, 2021, compared to $4.4 million for the year ended December 31, 2020. The increase was primarily the result of increased external research and development costs related to the clinical programs for PF614 and PF614-MPAR™. We do not currently track expenses on a program-by-program basis. We expect research and development expenses to increase in the future due to planned clinical trials and higher preclinical and clinical development costs for our product candidates.

General and Administrative Expenses

General and administrative expenses were $18.7 million for the year ended December 31, 2021, compared to $1.2 million for the year ended December 31, 2020. The increase was primarily driven by a one-time $11.6 million non-cash expense related to warrants issued for the share subscription facility, reflecting the fair value of 1,106,108 warrants issued with an exercise price of $10.01 per share in July 2021, based on the $14.49 share price on the date of issuance. Also contributing to the increase was $1.3 million of non-cash expense for consultants and $1.1 million expense for commitment fees for the share subscription facility. Excluding the one-time expenses related to the share subscription facility, which were recorded due to the uncertainty of future issuance of shares under the facility, and consultant expenses, we expect our general and administrative expenses to increase in the future due to increased director and officer insurance costs and various expenses related to operating as a public company.

Other Income and Expense

The change in fair value of derivative liabilities was an increase of $0.7 million for the year ended December 31, 2021, compared to an increase of $2.4 million for the year ended December 31, 2020. The change resulted from changes in the likelihood of realization of the embedded derivative instrument in previous convertible notes payable.

Interest expense was $1.3 million for the year ended December 31, 2021, compared to $1.0 million for the year ended December 31, 2020. The totals primarily reflect stated interest expense and debt discount accretion for the convertible notes converted upon the closing of the Merger on June 30, 2021.

The remaining elements of other income and expense primarily relate to the 2021 Notes, reflecting issuance costs and changes in valuation of the notes and related warrants. There was no corresponding activity in the year ended December 31, 2020.

Liquidity and Capital Resources

Sources of Liquidity and Capital

As of December 31, 2021, we had $12.3 million of cash and cash equivalents. Since inception, we have generated limited revenues and have incurred significant operating losses and negative cash flows from our operations, and we anticipate that we will continue to incur losses for at least the foreseeable future. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. As of December 31, 2021, we had an accumulated deficit of $85.8 million.

We have funded our operations to date primarily with proceeds from the sale of common equity, funding under federal research grants and borrowings under promissory notes. To fund future operations, we will need to raise additional capital. The amount and timing of future funding requirements will depend on many factors, including the timing and results of our ongoing research and development efforts and related general and administrative support. We anticipate that we will fund our operations through public or private equity or debt financings or other sources, such as potential collaboration agreements. We cannot make assurances that anticipated additional financing will be

available to us on favorable terms, if at all.

Remaining funding under two approved federal research grants totals $4.3 million and is expected to be utilized by December 31, 2022. Pursuant to the terms and conditions of the two grants, we are required to submit progress reports to NIDA on an annual basis and a final research performance progress report within 120 days of the performance period end date. Additionally, the grants limit the use of funds to activities that are clearly severable and independent from activities that involve human subjects until the receipt by NIDA of (i) Institutional Review Board ("*IRB*") approval, (ii) federal-wide assurance from the Office for Human Research Protections, (iii) a Data and Safety Monitoring Plan, (iv) certification that all key personnel have completed education on the protection of human subjects and (v) a Clinical Trials Dissemination Plan. We must also comply with the data sharing policies of NIDA and the NIH Public Access Policy, that require submission of final peer-reviewed journal manuscripts that arise from the use of grants to PubMed Central immediately upon acceptance for publication.

Neither grant has to be repaid. To receive the remaining funding for each respective study covered by a grant, we must meet certain milestones. We have met the required milestones under the MPAR Grant. The remaining milestone under the OUD Grant is identification of a R-methadone-TAAP clinical candidate that meet the specified criteria.

Inventions arising from the research projects funded with the grants are required to be reported to NIDA, per the Bayh-Dole Act (the Patent and Trademark Law Amendments Act), that permits us to retain ownership of the inventions, while also giving NIDA the license to practice the subject invention. In turn, we are expected to file for patent protection and to ensure commercialization upon licensing for the benefit of public health.

Pursuant to the GEM Agreement, we are entitled to draw down up to $60.0 million of gross proceeds ("*Aggregate Limit*") from GEM Global in exchange for shares of our common stock, subject to meeting the terms and conditions of the GEM Agreement. This share subscription facility is available for a period of 36 months from the closing date of the Merger. A draw down is subject to limitations on the amount that is drawn under the facility and must comply with certain conditions precedent including the listing of our shares on a principal market (which includes Nasdaq), having the necessary number of shares that are issuable pursuant to the draw down registered under an effective registration statement, and other notice and timing requirements. Upon our valid exercise of a draw down, pursuant to delivery of a notice and in accordance with other conditions, GEM Global is required to pay, in cash, a per-share amount equal to 90% of the average closing bid price of the shares of our common stock recorded by Nasdaq during the 30 consecutive trading days commencing on the first trading day that is designated on the draw down notice. In no event may our draw down requests exceed 400% ("*Draw Down Limit*") of the average daily trading volume for the 30 trading days immediately preceding the date we deliver the draw down notice. Our ability to utilize this share subscription facility is restricted while the 2021 Notes are outstanding.

Upon the closing of the Merger, GEM Global became entitled to a commitment fee in the form of cash or freely tradeable shares of our common stock in an amount equal to 2% of the Aggregate Limit or $1.2 million to be paid in two tranches. The commitment fee for the first tranche, which is equal to 67% of the commitment fee, or $800,000, becomes payable on the first anniversary of the closing of the Merger and the commitment fee for the second tranche, which is equal to the remaining 33% of the commitment fee, or $400,000, becomes payable on the eighteen-month anniversary of the closing of the Merger.

Additionally, we issued a warrant with a 36-month term at the closing of the Merger granting GEM Global the right to purchase 1,106,108 shares of our common stock (an amount equal to 4% of the total number of our common stock outstanding as of the closing date of the Merger (subject to adjustments described below), calculated on a fully diluted basis), at a strike price per share equal to $10.01, which was the closing bid price for such common stock on the first day of trading on Nasdaq. The strike price was reduced to $4.50 per share at December 31, 2021 because of a pricing adjustment per the GEM Agreement. The warrant can be exercised on a cashless basis in part or in whole at any time during the term. Any failure by us to timely transfer the shares under the warrant pursuant to GEM Global's exercise will entitle GEM Global to compensation in addition to other remedies. The number of shares underlying the warrant as well as the strike price is subject to adjustments for recapitalizations, reorganizations, change of control, stock split, stock dividend, reverse stock splits, and issuances of additional common shares at a price per share less than the exercise price.

The GEM Agreement contains certain negative covenants restricting us from securing an share subscription line similar to the financing provided under the GEM Agreement and requiring prompt notice of events constituting an alternate transaction. An "alternate transaction" includes an issuance of common stock at a price less than the then current market price, an "at-the-market" offering of securities, and an issuance of options, warrants, or similar rights of subscription or the issuance of convertible equity or debt securities. See "*Risks Related to Our Business, Financial Condition and Capital Requirements*" for additional information.

Finally, pursuant to the terms of the GEM Agreement, we are required to indemnify GEM Global for any losses it incurs as a result of a breach by us or of our representations and warranties and covenants under the GEM Agreement or for any misstatement or omission of a material fact in a registration statement registering those shares pursuant to the GEM Agreement. Also, GEM Global is entitled to be reimbursed for legal or other costs or expenses reasonably incurred in investigating, preparing, or defending against any such loss.

On September 24, 2021, we entered into the SPA for an aggregate financing of $15.0 million with institutional investors. A first closing under the SPA occurred on September 24, 2021 and a second closing under the SPA occurred on November 5, 2021. At the first closing, the Company issued to the investors (i) 2021 Notes in the aggregate principal amount of $5.3 million for an aggregate purchase price of $5.0 million and (ii) warrants to purchase 361,158 shares of the Company's common stock in the aggregate at an exercise price of $7.63 per share. At the second closing, the Company issued to the institutional investors referenced above, (i) 2021 Notes in the aggregate principal amount of $10.6 million for an aggregate purchase price of $10.0 million and (ii) warrants to purchase 722,317 shares of the Company's common stock in the aggregate at an exercise price of $7.63 per share.

Cash Flows for the years ended December 31, 2021 and 2020

The following table summarizes our cash flows for each of the periods presented:

	Year Ended December 31,	
	2021	**2020**
Net cash used in operating activities	$ (8,242,177)	$ (1,247,342)
Net cash provided by financing activities	20,312,699	1,100,020
Net increase (decrease) in cash and cash equivalents	$ 12,070,522	$ (147,322)

Operating Activities

During the years ended December 31, 2021 and 2020, we used cash in operating activities of $8.2 million and $1.2 million, respectively, primarily resulting from the clinical advancement of our product candidates, the timing of vendor invoicing and payments, legal and accounting fees, and increased costs related to operating as a public company.

Financing Activities

During the years ended December 31, 2021 and 2020, net cash provided by financing activities was $20.3 million and $1.1 million, respectively. The increase consisted

primarily of net proceeds from the Merger in June 2021 and net proceeds from the issuance of the 2021 Notes.

Funding Requirements

Our primary use of cash is to fund operating expenses, primarily related to our research and development activities. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

We expect our expenses, excluding non-cash expenses to recognize the fair value of warrants and convertible notes, to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, upon the completion of the Merger, we have incurred, and will continue to incur, additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other expenses that we did not incur as a private company. The timing and amount of our operating expenditures will depend largely on our ability to:

- advance preclinical development of our early-stage programs and clinical trials of our product candidates;
- manufacture, or have manufactured on our behalf, our preclinical and clinical drug material and develop processes for late state and commercial manufacturing;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own;
- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- obtain, maintain, expand and protect our intellectual property portfolio;
- manage the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- manage the costs of operating as a public company.

Our commitments as of December 31, 2021 included an estimated $13.0 million related to open purchase orders and contractual obligations that occurred in the ordinary course of business, including commitments with contract research organizations for multi-year pre-clinical and clinical research studies. Although open purchase orders are considered enforceable and legally binding, the terms generally allow us the option to cancel, reschedule, and adjust requirements based on our business needs prior to the delivery of goods or the performance of services.

Going Concern

We have generated limited revenues and have incurred significant operating losses since our inception and, as of December 31, 2021, we have an accumulated deficit of $85.8 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future.

Following the completion of the Merger and public listing of our common stock on Nasdaq, we had access to up to $60.0 million from a share subscription facility entered into in December 2020. The SPA for the 2021 Notes limits our ability to execute certain debt and equity financings, including our existing $60.0 million share subscription facility, while the notes are outstanding. Without the availability of proceeds through the share subscription facility, existing cash resources are not sufficient to allow us to fund current planned operations through the next 12 months following the filing of this Annual Report on Form 10-K, which raises substantial doubt about the Company's ability to continue as a going concern.

For additional information on risks associated with our substantial capital requirements, please read the section titled "*Risk Factors*" included elsewhere in this Annual Report on Form 10-K.

Working Capital

Because of the numerous risks and uncertainties associated with research, development and commercialization of biologic product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs, timing and ability to manufacture our product candidates to supply our clinical and preclinical development efforts and our clinical trials;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade product and necessary inventory to support commercial launch;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, expanding and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 to our audited consolidated financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when it has not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and makes adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors, including research laboratories, in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical studies and clinical trials; and
- CMOs in connection with drug substance and drug product formulation of preclinical studies and clinical trial materials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that supply, conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

Stock-Based Compensation

We measure all stock-based awards granted to employees, directors and non-employees based on their fair value on the date of the grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. We grant stock options and restricted stock awards that are subject to either service or market-based vesting conditions. Compensation expense related to awards to employees and non-employees with market-based vesting conditions is recognized based on the grant date fair value, which includes a probability assessment of the achievement of the market condition, over the requisite service period using the accelerated attribution method.

We classify stock-based compensation expense in our statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield.

Fair Value of Liabilities

We elected the fair value option to account for the 2021 Notes as we believe the fair value option provides users of the financial statements with greater ability to estimate the outcome of future events as facts and circumstances change, particularly with respect to changes in the fair value of the common stock underlying the conversion option. We use a Monte Carlo analysis to estimate the fair value of the conversion feature of the notes, which relies on unobservable Level 3 inputs. We use a discounted cash flow model to estimate the fair value of the debt component of the 2021 Notes. Changes in the fair value of the notes are recognized through other income (expense) for each reporting period.

Determination of the Fair Value of Common Stock

As there has historically been no public market for Former Ensysce common stock prior to the date of the closing of the Merger, the estimated fair value of Former Ensysce common stock was determined by our most recently available third-party valuations of common stock. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Our common stock valuations were prepared using an option pricing method ("*OPM*"). The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under the OPM method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. These third-party valuations were performed at various dates, which resulted in valuations of Former Ensysce common stock of $1.37 per share as of July 1, 2017, $1.82 per share as of February 28, 2018, $2.58 per share as of October 1, 2018, and $2.58 per share as of December 31, 2019 (prices adjusted for the exchange ratio of 0.06585 per the merger agreement).

In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the progress of our research and development programs, including the status and results of preclinical studies and clinical trials for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry;

- our financial position, including cash on hand, and our historical and forecasted performance and results of operations;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or our sale in light of prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the specialty biopharmaceutical industry.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

Shares of our common stock are now listed and trade on Nasdaq, so it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the publicly-traded quoted market price of our common stock.

Off-Balance Sheet Arrangements

We did not have during the periods presented, nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 3 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company under Section 107 of the JOBS Act, which provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to avail ourselves of the extended transition period and, therefore, while we are an emerging growth company we are not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies, unless we choose to early adopt a new or revised accounting standard.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common stock held by non-affiliates exceeds $250 million as of the prior June 30, or (ii) our annual revenues exceeded $100 million during such completed fiscal year and the market value of our common stock held by non-affiliates exceeds $700 million as of the prior June 30.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

We are exposed to market risk in the ordinary course of our business. These risks primarily relate to changes in interest rates and inflation.

Interest Rate Risk

Our cash and cash equivalents as of December 31, 2021 consisted of cash and a money market fund account. Because of the short-term nature of our money market fund, a sudden change in market interest rates would not be expected to have a material impact on our financial position or results of operations.

Inflation Risk

We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

Item 8. Financial Statements and Supplementary Data

The financial statements required by this Item are included in Item 15 of this report and are presented beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a–15(e) and 15d-15(e)) as of December 31, 2021. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were not effective as of December 31, 2021 due to the material weaknesses in our internal controls over financial reporting described below. Notwithstanding these material weaknesses, management has concluded that our consolidated financial statements included in this Annual Report on Form 10-K are fairly stated in all material respects in accordance with GAAP for each of the periods presented therein.

Management's Annual Report on Internal Control over Financial Reporting

As of December 31, 2021, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of

Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013) (the "2013 Framework"). In adopting the 2013 Framework, management assessed the applicability of the principles within each component of internal control and determined whether or not they have been adequately addressed within the current system of internal control and adequately documented. Based on this assessment, management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2021, our internal control over financial reporting was ineffective due to material weaknesses. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal controls over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses identified are insufficiently designed internal controls over period end financial reporting because of inadequate accounting expertise and insufficient level of supervision and review of unusual and/or infrequent transactions with complex or infrequently applied accounting topics due to the experience and limited number of accounting personnel in the financial reporting function.

We are taking steps to remediate the material weaknesses in our internal controls over financial reporting, including hiring a Chief Financial Officer in February 2021. Further, we plan to enhance our processes to identify and appropriately apply applicable accounting requirements to better evaluate and understand the nuances of the complex accounting standards that apply to our financial statements. Our plans at this time include providing enhanced access to accounting literature, research materials and documents and increased communication among our personnel and third-party professionals with whom we consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

The conclusion of the Company's principal executive officer and principal financial officer is based on the recognition that there are inherent limitations in all systems of internal control over financial reporting. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, errors or fraud. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. We were not required to have, nor have we, engaged our independent registered public accounting firm to perform an audit of internal control over financial reporting pursuant to SEC rules that permit us to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Executive Officers and Directors

Information required by this item, including information concerning the board of directors of the Company, the members of the Company's audit committee, the Company's audit committee financial expert, compliance with Section 16(a) of the Exchange Act and shareowner proposals, are incorporated by reference to the Company's Proxy Statement for the 2022 Annual Meeting of Shareowners, which will be filed with the SEC pursuant to Regulation 14A within 120 days after December 31, 2021. The information regarding executive officers is included in this report as Item 1 under the caption "*Identification of our Executive Officers*" and incorporated herein by reference.

Code of Business Conduct

We adopted a code of business conduct that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer, which is available on our website. Our code of business conduct is a "code of ethics," as defined in Item 406(b) of Regulation S-K. We will make any legally required disclosures regarding amendments to, or waivers of, provisions of our code of ethics on our website.

Item 11. Executive & Director Compensation

Information required by this Item is incorporated by reference from the Company's Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information required by this Item is incorporated by reference from the Company's Proxy Statement.

Item 13. Certain Relationships and Related Transactions and Director Independence

Information required by this Item is incorporated by reference from the Company's Proxy Statement.

Item 14. Principal Accountant Fees and Services

Information required by this Item is incorporated by reference from the Company's Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

Financial Statements

ENSYSCE BIOSCIENCES, INC.
CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

ENSYSCE BIOSCIENCES, INC.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of **Ensysce Biosciences, Inc.** ("Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company does not have revenue generating activities and is dependent on additional financing to fund operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding those matters are also described in Note 2 to the financial statements. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2017.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
March 31, 2022

Ensysce Biosciences, Inc.
Consolidated Balance Sheets

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 12,264,736	$ 194,214
Unbilled receivable	441,721	-
Right-of-use asset	24,721	23,538
Prepaid expenses and other current assets	2,931,415	130,124
Total current assets	15,662,593	347,876
Property and equipment, net	-	151
Other assets	754,756	3,780
Total assets	$ 16,417,349	$ 351,807
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 301,104	$ 1,724,598
Accrued expenses and other liabilities	3,407,533	344,792
Lease liability	24,874	25,500
Notes payable and accrued interest ($12,358,886 and $0 at fair value at December 31, 2021 and 2020, respectively)	12,748,155	4,245,082
Embedded derivative on convertible notes	-	670,262
Total current liabilities	16,481,666	7,010,234

Long-term liabilities:		
Notes payable, net of current portion (at fair value)	4,440,951	-
Other long term liabilities	3,652,790	-
Total long-term liabilities	8,093,741	-
Total liabilities	$ 24,575,407	$ 7,010,234
Commitments and contingencies (Note 6)		
Stockholders' deficit		
Preferred stock, $0.0001 par value, 1,500,000 shares authorized, no shares issued and outstanding at December 31, 2021 and December 31, 2020	-	-
Common stock, $0.0001 par value, 150,000,000 shares authorized; 24,662,904 and 15,768,725 shares issued at December 31, 2021 and December 31, 2020, respectively; 24,643,149 and 15,768,725 shares outstanding at December 31, 2021 and December 31, 2020, respectively	2,464	1,577
Additional paid-in capital	77,964,860	49,516,337
Accumulated deficit	(85,845,567)	(55,958,716)
Total Ensysce Biosciences, Inc. stockholders' deficit	(7,878,243)	(6,440,802)
Noncontrolling interests in stockholders' deficit	(279,815)	(217,625)
Total stockholders' deficit	(8,158,058)	(6,658,427)
Total liabilities and stockholders' deficit	$ 16,417,349	$ 351,807

The accompanying notes are an integral part of these consolidated financial statements.

Ensysce Biosciences, Inc.
Consolidated Statements of Operations

	Year Ended December 31,	
	2021	**2020**
Federal grants	$ 3,531,199	$ 3,931,209
Operating expenses:		
Research and development	4,690,082	4,389,579
General and administrative	18,711,548	1,154,917
Total operating expenses	23,401,630	5,544,496
Loss from operations	(19,870,431)	(1,613,287)
Other income (expense):		
Change in fair value of derivative liabilities	673,314	2,447,908
Issuance costs for convertible notes	(1,920,158)	-
Change in fair value of convertible notes	(2,993,060)	-
Issuance of liability classified warrants	(1,865,403)	-
Change in fair value of liability classified warrants	(1,438,186)	-
Interest expense	(1,295,307)	(995,496)
Other income and expense, net	(436,670)	-
Total other income (expense), net	(9,275,470)	1,452,412
Net loss	$ (29,145,901)	$ (160,875)
Net loss attributable to noncontrolling interests	(62,190)	(217,645)
Deemed dividend related to warrants down round provision	(803,140)	-
Net income (loss) attributable to common stockholders	$ (29,886,851)	$ 56,770
Net income (loss) per basic share:		
Net income (loss) per share attributable to common stockholders, basic	$ (1.48)	$ -
Weighted average common shares outstanding, basic	20,164,503	15,768,725
Net income (loss) per diluted share:		
Net income (loss) per share attributable to common stockholders, diluted	$ (1.48)	$ -
Weighted average common shares outstanding, diluted	20,164,503	16,507,387

The accompanying notes are an integral part of these consolidated financial statements.

Ensysce Biosciences, Inc.
Consolidated Statements of Changes in Stockholders' Deficit

	Stockholders' Equity (Deficit)					
	Common Stock		Additional			
	Number of Shares	Amount	Paid-In Capital	Accumulated Deficit	Noncontrolling interests	Total
Balance on December 31, 2019 (as previously reported)	239,465,160	**$ 5,987**	**$ 49,333,248**	**$ (56,015,486)**	**$ -**	**$ (6,676,251)**
Retroactive application of recapitalization	(223,696,435)	(4,410)	4,410	-	-	-
Balance on December 31, 2019, effect of reverse recapitalization (Note 2)	15,768,725	**$ 1,577**	**$ 49,337,658**	**$ (56,015,486)**	**$ -**	**$ (6,676,251)**
Stock-based compensation	-	-	178,679	-	-	178,679
Contribution from noncontrolling interest	-	-	-	-	20	20
Net loss	-	-	-	56,770	(217,645)	(160,875)

Balance on December 31, 2020	15,768,725	**$ 1,577**	**$ 49,516,337**	**$ (55,958,716)**	**$ (217,625)**	**$ (6,658,427)**
Exercise of stock options	284,825	28	262,834	-	-	262,862
Settlement of convertible notes in business combination	1,357,968	136	5,696,567	-	-	5,696,703
Conversion of convertible notes	387,363	39	2,247,576	-	-	2,247,615
Issuance of common stock for business combination, net of transaction costs	6,844,268	684	7,694,580	-	-	7,695,264
Stock-based compensation	-	-	121,764	-	-	121,764
Issuance of warrants	-	-	11,565,472	-	-	11,565,472
Warrants modification	-	-	56,590	-	-	56,590
Deemed dividend related to warrants down round provision	-	-	803,140	(803,140)	-	-
Net loss	-	-	-	(29,083,711)	(62,190)	(29,145,901)
Balance on December 31, 2021	24,643,149	**$ 2,464**	**$ 77,964,860**	**$ (85,845,567)**	**$ (279,815)**	**$ (8,158,058)**

The accompanying notes are an integral part of these consolidated financial statements.

Ensysce Biosciences, Inc.
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (29,145,901)	$ (160,875)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	151	201
Accrued interest	349,339	381,886
Accretion of discounts on promissory notes	945,969	613,610
Change in fair value of derivative liability	(673,314)	(2,447,908)
Change in fair value of convertible debt	2,993,060	-
Loss on extinguishment of debt	347,566	-
Stock-based compensation	121,764	178,679
Issuance of liability classified warrants	1,865,403	-
Change in fair value of liability classified warrants	1,438,186	-
Issuance of warrants for share subscription facility	11,565,472	-
Commitment fee for share subscription facility	1,124,289	-
Warrant modification	56,590	-
Lease cost	(1,808)	1,962
Issuance costs for convertible notes	1,920,158	-
Debt conversion expense	154,391	-
Changes in operating assets and liabilities:		
Unbilled receivable	(441,721)	173,552
Prepaid expenses and other assets	(1,616,019)	(25,401)
Accounts payable	(1,423,494)	1,183,820
Accrued expenses and other liabilities	2,177,742	(1,146,868)
Net cash used in operating activities	(8,242,177)	(1,247,342)
Cash flows from financing activities:		
Proceeds from issuance of convertible notes	14,029,842	1,000,000
Proceeds from issuance of promissory notes to related parties	350,000	100,000
Repayment of promissory notes	(467,774)	-
Proceeds from exercise of stock options	262,862	-
Proceeds from issuance of common stock for business combination, net of transaction costs	6,626,312	-
Repayment of financed insurance premiums	(488,543)	-
Contribution from noncontrolling interests	-	20
Net cash provided by financing activities	20,312,699	1,100,020
Increase (Decrease) in cash and cash equivalents	12,070,522	(147,322)
Cash and cash equivalents beginning of period	194,214	341,536
Cash and cash equivalents end of period	$ 12,264,736	$ 194,214
Supplemental cash flow information:		
Income tax payments	$ 1,600	$ 1,600
Supplemental disclosure of non-cash investing and financing activities:		
Fair value of derivative liability at issuance	$ 3,052	$ 471,758
Settlement of convertible notes into common stock	$ 5,696,703	$ -
Conversion of 2021 Notes	$ 2,093,224	$ -
Net assets acquired in business combination	$ 1,068,950	$ -
Financed insurance premiums, net	$ 867,300	$ -
Share subscription facility transaction costs	$ 12,689,764	$ -
Deemed dividend related to warrants down round provision	$ 803,140	$ -

The accompanying notes are an integral part of these consolidated financial statements.

Ensysce Biosciences, Inc.
Notes to the Consolidated Financial Statements

NOTE 1 – ORGANIZATION AND PRINCIPAL ACTIVITIES

Ensysce Biosciences, Inc. ("Ensysce"), along with its subsidiary, Covistat Inc. ("Covistat") and its wholly owned subsidiaries EBI Operating, Inc. and EBI OpCo. Inc. (collectively, the "Company"), is engaged in the development of drug delivery platforms targeting pain and cancer markets. The primary focus of the Company is its program developing abuse and overdose resistant pain technology with a clinical stage program being the abuse resistant, TAAP (Trypsin Activated Abuse Protection) opioid product candidate, PF614. In addition, the Company is developing its MPAR™ (Multi-Pill Abuse Resistant) technology for overdose protection which will be applied to the PF614 program. The Company is also applying its TAAP and MPAR™ technology to a methadone prodrug for use in the treatment of Opioid Use Disorder.

On January 31, 2021, Leisure Acquisition Corp., a Delaware corporation ("LACQ"), entered into an Agreement and Plan of Merger (as amended, the "Merger Agreement") with Ensysce Biosciences, Inc., a Delaware corporation ("Former Ensysce"), and EB Merger Sub, Inc., a Delaware corporation and wholly-owned, direct subsidiary of LACQ ("Merger Sub"). Pursuant to the Merger Agreement, on June 30, 2021 (the "Closing Date"), Merger Sub was merged with and into Former Ensysce, with Former Ensysce surviving the merger ("Merger" and, together with the other transactions contemplated by the Merger Agreement, the "Business Combination"). In connection with the closing of the Business Combination on the Closing Date (the "Closing"), Former Ensysce became a wholly owned subsidiary of LACQ and the stockholders of Former Ensysce, as of immediately prior to the effective time of the Merger, received shares of LACQ and hold a portion of the shares of Common Stock, par value $0.0001 per share (the "Common Stock"), of LACQ.

On the Closing Date, at the effective time of the Merger, LACQ changed its name from "Leisure Acquisition Corp." to "Ensysce Biosciences, Inc." Unless the context otherwise requires, "we," "us," "our" and the "Company" refer to Ensysce and the combined company and its subsidiaries following the Closing. Unless the context otherwise requires, references to "LACQ" refer to Leisure Acquisition Corp., a Delaware corporation, prior to the Closing.

In connection with the Business Combination, outstanding shares of common stock of Former Ensysce (including shares resulting from the conversion of Former Ensysce's convertible debt prior to Closing) were converted into the right to receive shares of Ensysce at an exchange ratio of 0.06585. Immediately following the Business Combination, stockholders of Former Ensysce owned approximately 71.8% of the outstandingcommon stock of the combined company. In addition, Former Ensysce's existing options and warrants were exchanged for equivalent securities in Ensysce on their existing terms (with standard adjustments to exercise price and underlying shares, consistent with the foregoing exchange ratio). As of July 2, 2021, Ensysce's shares of common stock are traded on the Nasdaq Capital Market ("Nasdaq") under the new ticker symbol "ENSC".

In June 2020, the Company commenced an initiative to develop a therapeutic for the treatment of certain coronavirus infections through the formation of a separate entity, Covistat, Inc., a Delaware corporation. Pursuant to the articles of incorporation, Covistat was authorized to issue 1,000,000 shares of common stock, $0.001 par value per share, and 100,000 shares of preferred stock, $0.001 par value per share. Ensysce is a 79.2% stockholder in Covistat, with 19.8% and 1.0% of the shares held by certain key personnel of the Company and an unrelated party, respectively.

In March 2020, the World Health Organization declared the outbreak of a respiratory disease caused by a new coronavirus as a "pandemic". First identified in late 2019 and known now as COVID-19, the outbreak has impacted millions of individuals worldwide. In response, many countries have implemented measures to combat the outbreak which have impacted global business operations. As of the date of issuance of the consolidated financial statements, the Company's operations have not been significantly impacted; however, the Company continues to monitor the situation. No impairments were recorded as of the balance sheet date as no triggering events or changes in circumstances had occurred as of year-end; however, due to significant uncertainty surrounding the situation, management's judgment regarding this could change in the future. In addition, while the Company's results of operations, cash flows and financial condition could be negatively impacted, the extent of the impact cannot be reasonably estimated at this time.

The Company currently operates in one business segment, which is pharmaceuticals. The Company is not organized by market and is managed and operated as one business. A single management team reports to the chief operating decision maker, the Chief Executive Officer.

NOTE 2 - BASIS OF PRESENTATION

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the United States Securities Exchange Commission ("SEC"). The consolidated financial statements include the accounts of Ensysce Biosciences, Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated in the consolidation.

Business Combination

The Business Combination was accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, LACQ was identified as the acquired company for financial reporting purposes, primarily because the stockholders of Former Ensysce control the majority of the voting power of the combined company, Former Ensysce's board of directors comprise a majority of the governing body of the combined company, and Former Ensysce's senior management comprise the leadership of the combined company. Accordingly, for accounting purposes, the transaction was treated as the equivalent of Former Ensysce issuing shares for the net assets of LACQ, accompanied by a recapitalization. The net assets of LACQ, primarily consisting of cash of $7.8 million and prepaid expenses of $1.1 million, were recorded at historical cost with no goodwill or other intangible assets recorded. The shares and net loss per share prior to the reverse recapitalization have been retroactively restated to reflect the exchange ratio of 0.06585. The consolidated financial statements reflect the historical operations of Ensysce.

The Business Combination triggered the conversion of the 2015 convertible notes, the 2018 convertible notes and the 2021 convertible note of Former Ensysce into common stock. In connection with the Closing, the 2020 convertible notes were amended to provide for automatic conversion of the outstanding principal and interest into shares of common stock of Ensysce. The Company had recorded $1.2 million of deferred transaction costs, consisting of legal and accounting fees directly related to the Business Combination, which were offset against the proceeds of the Business Combination within additional paid-in capital.

Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business.

The Company has not generated any product revenue and had an accumulated deficit of $85.8 million at December 31, 2021. There is no assurance that profitable operations will ever be achieved, and, if achieved, would be sustained on a continuing basis. Product development activities, clinical and pre-clinical testing, and commercialization of the Company's product candidates are necessary to develop the Company's products and will require significant additional financing. There can be no assurance the Company will be able to obtain such funds. These matters, among others, raise substantial doubt about the Company's ability to continue as a going concern.

In December 2020, the Company executed a share subscription facility with an investment group. Under the agreement, the investor agreed to provide the Company with a share subscription facility of up to $60.0 million for a 36-month term following the public listing of the Company's common stock. The Company will control the timing and maximum amount of drawdown under this facility and has no minimum drawdown obligation. The investor will pay, in cash, a per-share amount equal to 90% of the average daily closing price of the Company's stock during the 30 consecutive trading days prior to the issuance of a draw notice, which shall not exceed 400% of the average trading volume for the 30 trading days immediately preceding the draw down date. On June 30, 2021, the Company consummated the Business Combination with LACQ, resulting in the Company's shares becoming publicly listed on Nasdaq on July 2, 2021. Concurrent with the public listing of the Company's shares, the Company issued to the investor

1,106,108 warrants with a five-year term to purchase common stock of Ensysce at an exercise price of $10.01 per share (Notes 3 and 8), subject to a down round feature that would adjust the exercise price if other shares are issued below $10.01 per share. The Company must pay a commitment fee to the investor of $1.2 million with $800,000 due on the first anniversary of the public listing date and $400,000 due on the 18-month anniversary of the public listing date. The commitment fee can be paid from the proceeds of a draw against the facility or in freely tradable common stock of the Company.

In September 2021, the Company entered into a $15.9 million convertible note financing agreement with institutional investors (the "2021 Notes"). The financing provided for two closings, the first closed in September for $5.3 million and the second closed in November for $10.6 million. (See Note 7 for additional information.) The agreement limits the Company's ability to execute certain debt and equity financings, including its existing $60.0 million share subscription facility, while the convertible notes are outstanding. Without the availability of proceeds through the share subscription facility, existing cash resources are not sufficient to fund current planned operations. While the Company believes in the viability of its strategy to ultimately realize revenues and in its ability to raise additional funds, management cannot be certain that additional funding will be available on acceptable terms, or at all. The Company's ability to continue as a going concern is dependent upon its ability to obtain adequate financing and achieve profitable operations. As a result, these plans do not alleviate substantial doubt about the Company's ability to continue as a going concern for a period of 12 months following the date these consolidated financial statements were issued.

The consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates and Assumptions

Preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and disclosed in the accompanying notes. Actual results may differ from those estimates and such differences may be material to the consolidated financial statements. The more significant estimates and assumptions by management include, but are not limited to, the expense recognition for certain research and development services, the valuation allowance of deferred tax assets resulting from net operating losses, the estimated fair values of common stock, warrants and options to purchase the Company's common stock, and convertible notes payable.

Cash and Cash Equivalents

For purposes of the consolidated balance sheets and consolidated statements of cash flows, the Company considers all highly liquid instruments with maturity of three months or less at the time of issuance to be cash equivalents.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Cash and cash equivalents are financial instruments that are potentially subject to concentrations of credit risk. The Company's cash and cash equivalents are deposited in accounts at large financial institutions, and amounts may exceed federally insured limits. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash and cash equivalents are held. The Company has no financial instruments with off-balance sheet risk of loss.

Property and Equipment

Property and equipment include office and laboratory equipment that is recorded at cost and depreciated using the straight-line method over the estimated useful lives of five to six years. Depreciation expense of $151 and $201 was recognized for year ended December 31, 2021 and 2020, respectively. Depreciation expense is classified in general and administrative expense in the accompanying consolidated statements of operations.

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. For long-lived assets to be held and used, the Company will recognize an impairment loss only if the carrying amount is not recoverable through its undiscounted cash flows and measure any impairment loss based on the difference between the carrying amount and estimated fair value. There were no such losses for the year ended December 31, 2021 and 2020.

Derivative Financial Instruments

The Company does not use derivative instruments to hedge exposures to interest rate, market, or foreign currency risks. The Company evaluates all of its financial instruments, including notes payable, to determine whether such instruments are derivatives or contain features that qualify as embedded derivatives. Embedded derivatives must be separately measured from the host contract if all the requirements for bifurcation are met. The assessment of the conditions surrounding the bifurcation of embedded derivatives depends on the nature of the host contract and the features of the derivatives. Bifurcated embedded derivatives are recognized at fair value, with changes in fair value recognized in the consolidated statement of operations each period. Bifurcated embedded derivatives are classified with the related host contract in the Company's consolidated balance sheet.

Between January 2018 and January 2021, the Company entered into a series of notes that were determined to have embedded derivative instruments in the form of a contingent put option. The notes were recognized at the value of proceeds received after allocating issuance proceeds to the bifurcated contingent put option. The notes were subsequently measured at amortized cost using the effective interest method to accrete interest over their term to bring the notes' initial carrying value to their principal balance at maturity. The bifurcated put option was initially measured at fair value and subsequently measured at fair value with changes in fair value recognized as a component of other expenses in the consolidated statements of operations (see Note 7). The notes and the contingent put option are classified as either long-term or short-term liabilities based on the maturity date of the related loan.

All outstanding derivative liabilities were settled in connection with the conversion of outstanding notes payable on June 30, 2021. Refer to Note 7 for details of the conversion.

Fair Value Measurement

ASC 820, *Fair Value Measurements*, ("ASC 820") provides guidance on the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between willing market

participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance classifies fair value measurements in one of the following three categories for disclosure purposes:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The Company evaluates assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them for each reporting period. This determination requires significant judgments to be made by the Company.

As of December 31, 2021 and 2020, the recorded values of cash and cash equivalents, prepaid expenses, accounts payable, and accrued expenses and other liabilities approximate their fair values due to the short-term nature of these items.

2021 Notes

On September 24 and November 5, 2021, the Company issued convertible notes with a face value of $5.3 million and $10.6 million, respectively. The Company elected the fair value option to account for the convertible notes as it believes the fair value option provides users of the financial statements with greater ability to estimate the outcome of future events as facts and circumstances change, particularly with respect to changes in the fair value of the common stock underlying the conversion option and redemption feature. The fair value estimate of the 2021 Notes was based on a discounted cash flow model and a Monte Carlo model, which represent Level 3 measurements. Significant assumptions include the discount rate used in the discounted cash flow model and the expected premium for conversion used in the Monte Carlo model. Changes in the fair value of the notes are recognized in other income (expense) for each reporting period. Refer to Note 7 for details of the terms and conditions of the 2021 Notes.

Convertible Notes Pre Business Combination (Contingent Put Option)

The carrying value of outstanding notes payable at December 31, 2020 approximates the estimated aggregate fair value as the embedded contingent put option is recognized at fair value and classified with the debt host. The put option allowed for certain notes payable to be converted into common stock, contingent upon completion of an equity financing transaction with gross proceeds above certain thresholds. The fair value estimate of the embedded put option was based on the probability-weighted discounted value of the put feature and represents a Level 3 measurement. Significant assumptions used to determine the fair value of the put feature include the estimated probability of exercise of the put option and the discount rate used to calculate fair value. The estimated probability of exercise is based on management's expectation for future equity financing transactions. The discount rate is based on the weighted average effective yield of notes payable previously issued by the Company, adjusted for changes in market yields of healthcare sector CCC-rated debt. As of December 31, 2020, assumptions included a probability of exercise of the put option of 10% and a discount rate of 42.9%. As noted above, all outstanding derivative liabilities were settled upon the conversion of outstanding notes payable upon the consummation of the Business Combination. Refer to Note 7 for details of the conversion.

Warrants

On September 24 and November 5, 2021, the Company issued liability classified warrants in connection with the issuance of the 2021 Notes. The warrants were liability classified due to certain cash settlement features and included in "Other long-term liabilities" on the consolidated balance sheets. The Company uses a Black Scholes model to estimate the fair value of the warrants. Changes in the fair value of the warrants are recognized in other income (expense) for each reporting period. Refer to Note 8.

The following tables present assets and liabilities measured and recorded at fair value on the Company's consolidated balance sheet as of December 31, 2021 and 2020. As of December 31, 2021, all contingent put options, associated with the pre-combination convertible notes, were settled upon conversion of the notes at the closing of the Business Combination.

	December 31, 2021			
	Total	**Level 1**	**Level 2**	**Level 3**
Fair value of convertible note	$ 16,799,837	$ -	$ -	$ 16,799,837
Liability classified warrants	3,303,588			3,303,588
Total	$ 20,103,425	$ -	$ -	$ 20,103,425

	December 31, 2020			
	Total	**Level 1**	**Level 2**	**Level 3**
Contingent put option	$ 670,262	$ -	$ -	$ 670,262
Total	$ 670,262	$ -	$ -	$ 670,262

The following table summarizes the change in fair value of the Company's Level 3 assets and liabilities for the year ended December 31, 2021:

	December 31, 2021			
	Total	**Contingent put option**	**Convertible note**	**Liability classified warrants**
Fair value, December 31, 2020	$ 670,262	$ 670,262	$ -	$ -
Additions	17,768,404	3,052	15,900,000	1,865,352
Conversions	(2,093,224)	-	(2,093,224)	-
Change in fair value	3,757,983	(673,314)	2,993,061	1,438,236

Fair value, December 31, 2021	$ 20,103,425	$ -	$ 16,799,837	$ 3,303,588

Federal Grants

In September 2018, the National Institutes of Health ("NIH") through the National Institute on Drug Abuse awarded the Company a research and development grant related to the development of its MPAR™ overdose prevention technology (the "MPAR Grant"). The total approved budget for the initial two-year period was approximately $5.4 million ($3.2 million and $2.2 million in years 1 and 2 respectively) of which the Company must contribute $1.1 million in the first year of the grant. In August 2019, the grant was amended such that the approved budget for the two-year period decreased to approximately $5.1 million ($2.1 million and $3.0 million in years 1 and 2, respectively). In June 2021, the Company received a Notice of Award for an additional $2.8 million of funding in year 3 under the MPAR Grant beginning July 1, 2021.

In September 2019, the NIH/National Institute on Drug Abuse awarded the Company a second research and development grant related to the development of its TAAP/MPAR™ abuse deterrent technology for Opioid Use Disorder (the "OUD Grant"). The total approved budget for the two-year period was approximately $1.4 million.

The Company recognizes revenue when costs related to the grants are incurred. The Company believes this policy is consistent with the overarching premise in Accounting Standards Codification Topic 606, *Revenue from Contracts with* Customers ("ASC 606"), applied by analogy, to ensure that it recognizes revenues to reflect the transfer of promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services, even though there is no "exchange" as defined in ASC 606. The Company believes the recognition of revenue as costs are incurred and amounts become due is analogous to the concept of transfer of control of a service over time under ASC 606.

The revenue recognized under the MPAR Grant and OUD Grant was as follows:

	December 31,	
	2021	2020
MPAR	$ 2,646,579	$ 3,037,234
OUD	884,620	893,975
Total	$ 3,531,199	$ 3,931,209

Amounts requested or eligible to be requested through the NIH payment management system, but for which cash has not been received, are presented as an unbilled receivable on the Company's consolidated balance sheet. As all amounts are expected to be remitted timely, no valuation allowances are recorded.

Research and Development Costs

The Company's research and development expenses consist primarily of third-party research and development expenses, consulting expenses, animal and clinical studies, and any allocable direct overhead, including facilities and depreciation costs, as well as salaries, payroll taxes, and employee benefits for those individuals directly involved in ongoing research and development efforts. Research and development expenses are charged to expense as incurred. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs associated with the Company's executive, finance, human resources, compliance, and other administrative personnel, as well as accounting and legal professional services fees.

Stock-based Compensation

The Company expenses stock-based compensation over the requisite service period based on the estimated grant-date fair value of the awards using a graded amortization approach. The Company accounts for forfeitures as they occur.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. For the year ended December 31, 2021 and 2020, stock-based compensation costs are recorded in general and administrative expenses in the consolidated statements of operations.

From time-to-time equity classified awards may be modified. On the modification date, the Company estimates the fair value of the awards immediately before and immediately after modification. The incremental increase in fair value is recognized as expense immediately to the extent the underlying equity awards are vested and on a straight-line basis over the same remaining amortization schedule as the unvested underlying equity awards.

Income Taxes

Income taxes are recorded in accordance with ASC 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company recognizes any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Earnings per Share

The basic earnings per share is calculated by dividing the Company's net income or loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. The diluted earnings per share is calculated by dividing the Company's net earnings attributable to common stockholders by the diluted weighted average number of common shares outstanding during the period, determined using the treasury stock method and the average stock price during the period. A reconciliation of the numerators and denominators of the basic and diluted earnings per share calculations follows :

	December 31,	
	2021	2020
Numerator:		
Net income (loss) attributable to common stockholders	$ (29,886,851)	$ 56,770
Denominator:		
Weighted average shares outstanding, basic	20,164,503	15,768,725
Weighted average dilutive stock options	-	738,662
Weighted average shares outstanding, diluted	20,164,503	16,507,387
Net income (loss) per share attributable to common stockholders, basic	$ (1.48)	$ 0.00
Net income (loss) per share attributable to common stockholders, diluted	$ (1.48)	$ 0.00

The following weighted average shares have been excluded from the calculations of diluted weighted average common shares outstanding because they would have been anti-dilutive:

	December 31,	
	2021	2020
Stock options	4,498,307	3,640,309
Warrants	10,273,755	19,755
Total	14,772,062	3,660,064

Recently Issued Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes ("ASU 2019-12"), which simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The guidance is effective for fiscal years beginning after December 31, 2021 and interim periods within that year. Early adoption is permitted. The Company is evaluating the impact of ASU 2019-12 on the consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, Debt – Debt with Conversion and Other Options (Topic 470) to address issues identified as a result of the complexity with applying GAAP for certain financial instruments with characteristics of liabilities and equity. The FASB decided to reduce the number of accounting models for convertible debt instruments and convertible preferred stock, resulting in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Certain types of convertible instruments will continue to be subject to separation models: (a) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (b) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. For convertible instruments, the contracts primarily affected are those with beneficial conversions or cash conversion features as the accounting models for those specific features have been removed. For contracts in an entity's own equity, the contracts primarily affected are freestanding instruments and embedded features that are accounted for as derivatives due to a failure to meet the settlement conditions of the derivatives scope exceptions. The FASB simplified the settlement assessment by removing the requirements to (a) consider whether the contract would be settled in registered shares, (b) to consider whether collateral is required to be posted, and (c) assess shareholder rights. The FASB also decided to enhance information transparency by making targeted improvements to the disclosures for convertible instruments and earnings-per-share guidance. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023 and early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. Entities must adopt the guidance as of the beginning of its annual fiscal year and a modified retrospective or fully retrospective transition approach is permitted. The Company is evaluating the impact of ASU 2020-06 on the consolidated financial statements.

NOTE 4 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2021	**2020**
Prepaid research and development	$ 2,124,008	$ 112,966
Prepaid insurance	733,234	17,158
Other prepaid expenses	74,173	-
Total prepaid expenses and other current assets	$ 2,931,415	$ 130,124

NOTE 5 – ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consisted of the following:

	December 31,	
	2021	**2020**
Share subscription facility commitment fees	$ 800,000	$ -
Professional fees	138,086	-
Accrued research and development	388,997	72,906
Accrued scientific advisory board fees	60,032	60,032
Consultant compensation expenses	1,342,479	-
Bonus accrual	610,000	-
Deferred grant revenue	-	159,047
Other accrued liabilities	67,939	52,807
Total accrued expenses and other liabilities	$ 3,407,533	$ 344,792

Other long-term liabilities consisted of the following:

	December 31, 2021	2020
Share subscription facility commitment fees	$ 349,202	$ -
Liability classified warrants	3,303,588	-
Total other long-term liabilities	$ 3,652,790	$ -

Ensysce Biosciences, Inc.
Notes to the Consolidated Financial Statements

NOTE 6 - COMMITMENTS AND CONTINGENCIES

Purchase Commitments

As of December 31, 2021, the Company's commitments included an estimated $13.0 million related to the Company's open purchase orders and contractual obligations that occurred in the ordinary course of business, including commitments with contract research organizations for multi-year pre-clinical and clinical research studies. Although open purchase orders are considered enforceable and legally binding, the terms generally allow the Company the option to cancel, reschedule, and adjust its requirements based on its business needs prior to the delivery of goods or the performance of services.

Litigation

As of December 31, 2021 and 2020, there were no pending legal proceedings against the Company that are expected to have a material adverse effect on cash flows, financial condition or results of operations. From time to time, the Company could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. Periodically, the Company reviews the status of significant matters, if any exist, and assesses its potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount can be estimated, the Company accrues a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict. Because of such uncertainties, accruals are based on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation.

On July 12, 2021, following the Business Combination with LACQ, the Company's former financial advisor filed an action against the Company and its Chief Executive Officer alleging that the common stock and warrants issued to the former advisor in satisfaction of its advisory fee should have been registered and immediately tradeable. On August 3, 2021, the parties entered into a settlement agreement whereby the former advisor would have their common stock and the common stock underlying their warrants registered on the Company's resale Registration Statement on Form S-1 that it filed on August 9, 2021 (the "Resale Registration Statement"). In addition, the warrants would be modified to allow for cashless exercise and to reduce the exercise price from $11.50/share to $10.00/share. In consideration for this, both parties agreed to release the other from any past, present, or future claims. In addition, the former advisor agreed to immediately stay the proceedings and inform the Superior Court of a conditional settlement and to dismiss the lawsuit with prejudice five days following the effectiveness of the Resale Registration Statement. On October 6, 2021, the Superior Court dismissed with prejudice the case filed on July 12, 2021 by the Company's former financial advisor, following effectiveness of the Resale Registration Statement filed on August 9, 2021 and amended on September 22, 2021.

Lease

During part of the year ended December 31, 2020, the Company leased office space on a month-to-month basis. In August 2020, the Company entered into an agreement to lease office space. The lease commencement date was October 1, 2020 and the lease was scheduled to terminate October 31, 2021 with no option to renew.

In August 2021, the Company entered into an amendment of the aforementioned lease, whereby the term of the lease was extended through October 31, 2022 with no option to renew. The amendment resulted in a modification of the lease under ASC 842 and the Company remeasured the lease liability as of the amendment date.

As of December 31, 2021, the future lease payments totaled $24,874.

The Company recognized total rent expense of $41,418 and $36,645 in the years ended December 31, 2021, and 2020, respectively.

Compensation Subject to Shareholder Approval

In July 2021, the Company engaged two consultants to perform certain public and investor relations services in consideration for warrants to purchase 500,000 shares of common stock with a five-year term and an exercise price of $6.28 each, 50,000 shares of common stock each, and 200,000 restricted stock units each. The restricted stock units vest over one year with 50% of the vesting contingent upon certain market conditions. These equity awards are contingent upon shareholder approval of an amended and restated 2021 Omnibus Plan at a special shareholder meeting in January 2022, whereby the warrants would be replaced by non-qualified stock options with similar terms. As the terms of the awards did not satisfy the grant date criteria for an equity award, as of December 31, 2021, the Company recorded a liability and an expense of $1,342,479 (to general and administrative expense on the consolidated statement of operations) to reflect the estimated value of services received during the period. See Note 12 for discussion of the special shareholder meeting in January 2022.

Ensysce Biosciences, Inc.
Notes to the Consolidated Financial Statements

NOTE 7 - NOTES PAYABLE

The following table provides a summary of the Company's outstanding debt as of December 31, 2021:

	Principal balance	Accrued interest	Fair value adjustment	Net debt balance
2021 Notes	$ 13,647,341	$ 159,435	$ 2,993,061	$ 16,799,837
Financed insurance	385,187	4,082	-	389,269
Total	$ 14,032,528	$ 163,517	$ 2,993,061	$ 17,189,106

The following table provides a summary of the Company's outstanding debt as of December 31, 2020:

	Principal balance	Accrued interest	Unamortized debt discount	Net debt balance
2015 convertible notes	$ 100,000	$ 28,671	$ -	$ 128,671
2018 convertible notes	3,500,000	727,905	(783,124)	3,444,781
2020 promissory notes	100,000	1,694	-	101,694
2020 convertible notes	700,000	29,726	(159,790)	569,936
Total	$ 4,400,000	$ 787,996	$ (942,914)	$ 4,245,082

The interest expense recognized for notes payable (excluding the 2021 Notes) was as follows:

	December 31,	
	2021	2020
Stated interest accrual	$ 251,857	$ 381,886
Debt discount accretion	945,969	613,610
Total	$ 1,197,826	$ 995,496

2015 Convertible Notes Payable

During 2015, the Company issued certain convertible promissory notes in the aggregate principal amount of $873,000. During 2017 and 2018, all but $100,000 were converted into common shares of Ensysce. The remaining convertible promissory note bears interest at 5% per annum, is due on demand (principal and interest) and is mandatorily convertible at a variable price per share equal to 80% of the price received in certain future equity transactions. The notes were converted into common stock in June 2021.

2018 Convertible Notes Payable

Between January 2018 and December 2020, the Company received financing totaling $3,500,000 under a series of unsecured promissory notes with a stockholder and board member ($2,500,000) and an unrelated party ($1,000,000). The promissory notes mature 24 months from the date of issuance and bear interest at the rate of 10% per annum. The promissory notes, together with all interest as accrued, can be converted into shares of Ensysce's common stock at the option of the noteholder, at 50% of the price paid per share for equity securities by the investors in a subsequent equity financing of no less than $5,000,000 gross proceeds (the "contingent put option"). The contingent put option is required to be bifurcated from the debt host and measured at fair value with changes in fair value recorded in earnings (see Note 3).

Additionally, if there is an initial public offering or reverse merger that results in Ensysce becoming publicly listed, the promissory notes automatically convert to equity at the lower of $0.25 per share or the then-current Enterprise Value per share (the "automatic conversion option"). Enterprise Value per Share is defined as market capitalization, debt and preferred stock less cash and cash equivalents divided by the common stock of Ensysce on the measurement date, not to exceed $55 million. The Company assessed whether the automatic conversion option should be accounted for separately from the debt host and concluded that as the common shares of Ensysce are currently not publicly traded and thus are not considered readily convertible to cash, the automatic conversion option cannot be net settled. Further, the conversion price of the promissory notes exceeded the per share fair value of Ensysce's common stock on each issuance date and, consequently, no beneficial conversion feature exists.

The 2018 convertible notes also include a change in control call option whereby, upon the close of a sale of Ensysce, other than an initial public offering, Ensysce has the right to prepay the promissory notes at 200% of the principal outstanding plus all accrued and unpaid interest. This call option is required to be bifurcated because it is considered to not be clearly and closely related to the debt host. However, the Company has concluded that as of each balance sheet date presented, the exercise of this call option is not probable and thus the call option has a de minimis value.

In June 2020, the board resolved to extend the maturity of all 2018 convertible notes payable issued in 2018 by one year. The Company did not incur legal fees or other additional costs to effect the modification. The modification met the criteria to be classified as a troubled debt restructuring under ASC 470-50. The effective interest rate was recalculated to reflect the modified expected term of the notes and no gain or loss was recognized.

The notes were converted into common stock in June 2021.

2020 Convertible Notes Payable

During the year ended December 31, 2020, Covistat received financing totaling $700,000 under a series of unsecured promissory notes with unrelated parties. The notes mature in July 2022 and bear interest at a rate of 10% per annum. The notes cannot be prepaid without the prior consent of the holder. The notes, together with all accrued and unpaid interest, are automatically convertible upon an initial public offering of Covistat shares or a private sale of a single class of Covistat's equity securities with gross proceeds of at least $2.0 million within a 12-month period. The notes are convertible at the option of the holder at maturity. With respect to an automatic conversion, the conversion price will be the lesser of (a) 80% of the per-share price of the equity securities sold or (b) the price equal to $10.0 million divided by the aggregate number of shares of Covistat's common stock immediately prior to the initial closing of such financing. With respect to an optional conversion, the conversion price will be the price equal to $10.0 million divided by the aggregate number of shares of Covistat's common stock immediately prior to the initial closing of such financing. The conversion feature is required to be bifurcated from the debt host and measured at fair value with changes in fair value recorded in earnings (see Note 3). The notes were converted into common stock in June 2021.

2020 Promissory Notes Payable

During the year ended December 31, 2020, the Company received financing totaling $100,000 under a series of unsecured promissory notes with the Chief Executive Officer and a board member. The promissory notes bear interest at a rate of 10% per annum and mature December 31, 2021 or upon certain financing transactions, whichever is earlier. The notes were repaid in full in July 2021.

2021 Convertible Note Payable

In January 2021, the Company received financing totaling $50,000 under an unsecured convertible note. The convertible note bears interest at a rate of 10% per annum and matures January 28, 2023. The promissory note, together with accrued interest, would be automatically converted into shares of Ensysce's common stock at 80% of the price paid per share for equity securities by investors in an IPO or equity financing of no less than $10.0 million gross proceeds. The conversion feature is required to be bifurcated from the debt host and measured at fair value with changes in fair value recorded in earnings (see Note 3). The note was converted into common stock in June 2021.

2021 Promissory Notes

In March and May 2021, the Company received financing totaling $350,000 under unsecured promissory notes issued to related parties including the Chief Executive Officer and members of the board of directors. The notes mature on the earlier of June 30, 2022 or the Company's receipt of gross proceeds of at least $2.0 million from the sale of common or preferred stock and bear interest at a rate of 10% per annum. The notes were repaid in full in July 2021.

Settlement of Convertible Notes Payable

On June 30, 2021, the Company consummated the Business Combination with LACQ, which triggered the automatic conversion into common stock of the 2015 convertible notes payable, the 2018 convertible notes payable, and the 2021 convertible note payable. In connection with certain closing conditions, the 2020 convertible notes were amended to provide for automatic conversion of the outstanding principal and interest into common stock. The modification resulted in a loss on extinguishment of debt of $347,566 based on the share price on the date of conversion and is recorded in other income (expense), net.

The Company applied ASC 470-20-40-1 to the accounting of the conversion, which requires the accelerated recognition of unamortized debt discounts as interest expense upon conversion. Accordingly, $554,911 of unamortized debt discount as of the June 30, 2021 conversion has been recognized as interest expense within the consolidated statement of operations.

The table below summarizes the conversion of each class of notes payable:

	Immediately prior to merger				
Note series	**Principal**	**Interest**	**Net carrying value of debt converted**	**Shares of common stock issued**	**Outstanding debt, June 30, 2021**
2015 Convertible Note	$ 100,000	$ 31,151	$ 131,151	15,116	$ -
2018 Convertible Notes	3,500,000	901,466	4,401,466	1,259,837	-
2020 Convertible Notes	700,000	64,438	764,438	77,000	-
2021 Convertible Note	50,000	2,082	52,082	6,015	-
Total	$ 4,350,000	$ 999,137	$ 5,349,137	1,357,968	$ -

September 2021 Convertible Notes Payable

On September 24, 2021, the Company entered into an agreement with institutional investors to issue the 2021 Notes. The agreement provides for two closings: the first closing for $5.3 million (resulting in net proceeds of $4.6 million) which closed on September 24, 2021 (the "First Closing"). The second closing for $10.6 million (resulting in net proceeds of $9.4 million) which closed on November 5, 2021 (the "Second Closing").

The proceeds of the sale of the securities shall be used for working capital purposes subject to certain customary restrictions and secured by the Company's rights to its patents and licenses. The Company may not issue any additional debt or equity without the prior written consent of the holders.

The 2021 Notes mature on June 23, 2023 for the first closing, and August 4, 2023 for the second closing. The notes bear interest at a rate of 5% per annum, in addition to an original issue discount of 6%. The interest may be settled in cash or shares at the option of the Company and is payable together with monthly redemptions of the outstanding principal amount of the debt.

The Company elected to apply the fair value option to the measurement of the 2021 Notes. The total initial fair value of the debt at issuance was $15.9 million. The Company recorded total issuance costs of $1,920,158, representing investment banking and legal fees of $1,020,158 and original issue discounts of $900,000. After several conversions occurring prior to year-end (discussed below), the Company remeasured the fair value as of December 31, 2021 and recognized an expense of $3.0 million as the fair value of the 2021 Notes had increased to $16.8 million due to an increase in the value of the conversion option resulting from a decrease in the price of the Company's common stock. The December 31, 2021 fair value measurement includes the assumption of accrued interest and interest expense (at the stated rate plus an 8% cash settlement premium) and thus a separate amount is not reflected on the consolidated statements of operations. If presented separately, the total amount of interest expense (after consideration of the conversions) at December 31, 2021 would be $163,770.

The 2021 Notes may be converted into the Company's common stock at the option of the holder in whole or in part at the conversion price of $5.87, subject to a beneficial ownership limitation of 4.99% (subject to adjustment). The Company must reserve sufficient shares of authorized common stock to effect the conversion of the 2021 Notes and payment of interest. The shares were registered for public resale under a registration statement.

On December 23, 2021 the Company issued 255,537 shares of common stock in repayment of $1.5 million, the shares issued at the stated conversion price of $5.87. On December 27, 2021, the Company issued a Letter of Agreement amending the Securities Purchase Agreement to allow for conversion of the outstanding notes at an exercise price of $4.50 per share of the Company's common stock for fourteen trading days, commencing December 28, 2021 and ending January 14, 2022. Following this period, the initial conversion price of $5.87 was restored. On December 28, 2021 holders delivered separate notices of conversion for a total of $593,224 of principal in exchange for shares based on the amended conversion price of $4.50. The Company recorded an inducement expense equal to the excess fair value (utilizing the Company policy for conversions of average of the high and low share prices of the day) of the consideration transferred above the securities that would have been issued under the original conversion terms. The total debt conversion expense was $154,391 and is reflected in other income (expense), net.

At the Company's option, the Company may redeem some or all of the then-outstanding principal amount of the 2021 Notes for cash in an amount equal to 100% of the principal to be redeemed, plus accrued but unpaid interest, plus all other amounts due with respect to the 2021 Notes.

Beginning January 1, 2022 for the First Closing, and February 1, 2022 for the Second Closing, and the first of each subsequent month, terminating upon the full redemption of the 2021 Notes (each a "Monthly Redemption Date"), the Company shall redeem the Monthly Redemption Amount (defined below), payable in cash or shares. The number of shares to be settled shall be based on a conversion price equal to the lesser of (a) $5.87 and (b) 92% of the average of the three lowest volume-weighted average prices ("VWAP") during the 10 consecutive trading days prior to the applicable Monthly Redemption Date. The Company may not pay the Monthly Redemption Amount in shares unless the applicable conversion price is greater than or equal to $0.78 and the Company has been in compliance with customary requirements under the agreement, unless waived in writing by the holder.

The Monthly Redemption Amount is defined as 1/18th of the original principal amount, plus accrued but unpaid interest, plus any other amounts due to the holder with respect to the 2021 Notes. If the Company elects to settle such redemptions in shares, the Monthly Redemption Amount is calculated based on 92% of the average of the lowest three VWAPs in the ten trading days prior to the Monthly Redemption Date. If the Company elects to settle redemptions in cash, the Monthly Redemption Amount shall include an 8% premium of the Monthly Redemption Amount.

If, at any time while the 2021 Notes are outstanding, the Company carries out one or more capital raises in excess of $5.0 million, the holder has the right to require the Company to use up to 20% of the gross proceeds of such transaction to redeem all or a portion of the convertible notes for an amount in cash equal to the cash Mandatory Redemption Amount (i.e., 108% of outstanding principal and unpaid interest).

Financed Insurance Premiums

During year ended December 31, 2021, the Company financed its directors and officers' liability insurance in the amount of $867,300, of which $389,269 remains outstanding at December 31, 2021. The Company will pay a total of $12,078 in interest from inception through April 2022 when the note will be paid in full. The Company expensed $10,513 of interest for the year ended December 31, 2021.

NOTE 8 - STOCKHOLDERS' EQUITY

In June 2021, in connection with the Business Combination, the Company amended and restated its Certificate of Incorporation to authorize 150,000,000 shares of common stock and 1,500,000 shares of preferred stock, both with par value equal to $0.0001. As of December 31, 2021 and 2020, there were no shares of preferred stock issued and outstanding.

Common Stock

On June 30, 2021, in connection with the Business Combination, the following common stock activity occurred:

- 16,053,550 shares of common stock were issued to holders of Former Ensysce common stock.
- 6,219,268 shares of common stock outstanding were assumed by the Company.
- 1,357,968 shares of common stock were issued in settlement of $5.8 million of convertible debt.
- 19,755 shares of restricted common stock were issued in exchange for previously outstanding warrants to purchase Former Ensysce common stock.
- 500,000 shares of common stock were issued in settlement of a termination agreement with a strategic advisor dated January 2021.
- 125,000 shares of common stock were issued in settlement of deferred underwriting costs.

Warrants

In February 2013, the Company issued 13,170 warrants to purchase common stock, with a ten-year life and an exercise price of $6.23 per share. In August 2019, in connection with the issuance of convertible debt, the Company issued 6,585 warrants to purchase common stock, with a ten-year life and an exercise price of $3.04. As of December 31, 2020, the warrants remained outstanding. On June 30, 2021, the Company issued 19,755 shares of common stock in settlement of the warrants, with such shares subject to restriction until certain conditions are met.

On December 31, 2021, outstanding warrants to purchase shares of common stock are as follows:

Reference	Shares Underlying Outstanding Warrants		Exercise Price	Description	Classification
(a)	18,901,290	$	10.00 - 11.50	LACQ warrants	Equity
(b)	1,106,108	$	4.50	Share subscription facility	Equity
(c)	361,158	$	7.63	Convertible note	Liability
(d)	722,317	$	7.63	Convertible note	Liability
	21,090,873				

a) On June 30, 2021, as a result of the Closing, the Company assumed a total of 18,901,290 warrants previously issued by LACQ. The warrants provide holders the right to purchase common stock at a strike price of between $10.00 and $11.50 per share and expire June 30, 2026, five years following the completion of the Business Combination. A total of 10,000,000 of the outstanding warrants are public warrants which trade on the OTC Pink Open Market under the ticker symbol ENSCW. The remaining 8,901,290 warrants are private warrants with restrictions on transfer and which have the right to a cashless exercise at the option of the holder.

On August 3, 2021, the Company entered into an agreement with an existing warrant holder to reduce the price of 500,000 warrants issued on June 30, 2021 from $11.50 to $10.00, resulting in an incremental increase in their fair value of $56,591, recognized in general and administrative expense.

b) On July 2, 2021, upon public listing of the Company's shares, the Company issued 1,106,108 warrants to purchase common stock pursuant to the share subscription facility. The warrants have a three-year life and an exercise price of $10.01 per share. The grant date fair value of the warrants, based on the $14.49 stock price on the date of issuance, was $11.6 million, and was recognized in general and administrative expense due to the uncertainty of future issuance of shares under the share subscription facility.

On December 28, 2021, the exercise price of the warrants adjusted to $4.50 per share, as required by a down round adjustment feature of the warrant, due to common stock issued at a price below the then current exercise price. The difference in fair value of the existing warrant prior to the adjustment and the value of the warrant after (utilizing a "Black-Scholes model") is reflected on the consolidated statement of operations as a "deemed dividend".

c) On September 24, 2021, the Company issued 361,158 warrants in connection with the issuance of the 2021 Notes. The warrants were immediately exercisable with an exercise price of $7.63 (subject to downward revision protection in the event the Company makes certain issuances of common stock at prices below the conversion price) and expire on September 23, 2026.

d) On November 5, 2021, the Company issued 722,317 warrants in connection with the issuance of the 2021 Notes. The warrants were immediately exercisable with an exercise price of $7.63 (subject to downward revision protection in the event the Company makes certain issuances of common stock at prices below the conversion price) and expire on November 4, 2026.

The fair value of each warrant issued has been determined using the Black-Scholes option-pricing model. The material assumptions used in the Black-Scholes model in estimating the fair value of the warrants issued for the periods presented were as follows:

	(a) LACQ warrants (grant date varies)	(b) Share subscription facility (grant date 7/2/2021)	(c) Liability classified warrants (grant date 9/24/2021)	(c) Liability classified warrants (remeasured at 12/31/2021)	(d) Liability classified warrants (grant date 11/5/2021)	(d) Liability classified warrants (remeasured at 12/31/2021)
Stock price	$ 14.49	14.49	$ 4.49	$ 4.70	$ 2.25	$ 4.70
Exercise price	$ 10.0 - 11.50	10.01	$ 7.63	$ 7.63	$ 7.63	$ 7.63
Expected term (years)	3.00	3.00	5.00	4.75	5.00	4.85
Volatility	110.0%	110.0%	94.1%	97.4%	94.1%	96.8%
Risk free rate	0.5%	0.5%	1.0%	1.3%	1.0%	1.3%

NOTE 9 - STOCK-BASED COMPENSATION

In 2016, Former Ensysce adopted the Ensysce Biosciences, Inc. 2016 Stock Incentive Plan (the "2016 Plan"). The 2016 Plan, as amended, allowed for the issuance of non-statutory stock options, incentive stock options and other equity awards to Former Ensysce's employees, directors, and consultants.

In March 2019, Former Ensysce adopted the 2019 Directors Plan, which was amended in August 2020. The 2019 Directors Plan, as amended, allowed for the issuance of shares of Former Ensysce's common stock pursuant to the grant of non-statutory stock options.

In addition to the 2016 Plan and the 2019 Directors Plan, the Company has two legacy equity incentive plans (the "Legacy Plans"). No additional equity awards may be made under the Legacy Plans and the outstanding options will expire if unexercised by certain dates through August 2024.

In connection with the Business Combination, the Company assumed the 2021 Omnibus Incentive Plan (the "2021 Omnibus Plan"), which was approved by LACQ's board and subsequently LACQ's stockholders at a special stockholder meeting on June 28, 2021. The 2021 Omnibus Plan provides for the conversion with existing terms of the 4,444,068 options outstanding under Former Ensysce stock plans and reserves for issuance an additional 1,000,000 shares for future awards under the 2021 Omnibus Plan. No further awards may be made under the Former Ensysce stock plans.

As of December 31, 2021 and 2020, the options outstanding under each plan were as follows:

	December 31, 2021	December 31, 2020
Legacy Plans	-	543,106
2016 Plan	-	4,034,332
2019 Directors Plan	-	151,455
2021 Omnibus Plan	4,444,068	-
Total options outstanding	4,444,068	4,728,893

Option Activity

There were no stock option grants in 2021. During the year ended December 31, 2020, the Company granted stock options to purchase an aggregate of 131,700 shares of common stock to members of the board of directors under the 2019 Directors Plan. The options vest over three years and have an exercise price of $3.35 per share. The options were converted with their existing terms into the 2021 Omnibus Plan in connection with the Business Combination.

The Company recognized within general and administrative expense stock-based compensation expense of $121,764 and $178,679 for the year ended December 31, 2021 and 2020, respectively. During the year ended December 31, 2021 and 2020, there was no stock-based compensation allocated to research and development expense.

The following table summarizes the Company's stock option activity during the year ended December 31, 2021:

		Weighted average		
	Options	Exercise price	Remaining contractual life	Intrinsic value
Outstanding at December 31, 2020	4,728,893	$ 2.28	6.80	$ 1,817,383
Granted	-	-		-
Exercised	(284,825)	0.91		472,453
Expired / Forfeited	-	-		-
Outstanding at December 31, 2021	4,444,068	2.40	6.00	10,207,306
Exercisable at December 31, 2021	4,337,971	2.38	5.90	10,055,725
Vested and expected to vest	4,444,068	2.40	6.00	10,207,306

Option Valuation

The fair value of each stock option granted has been determined using the Black-Scholes option-pricing model. The material assumptions used in the Black-Scholes model in estimating the fair value of the options granted for the periods presented were as follows (there were no grants issued in 2021):

	December 31, 2020
Stock price	$ 2.58
Exercise price	$ 3.35
Expected stock price volatility	124.0%
Expected term (years)	5.8
Risk-free interest rate	.27 – 1.52%
Expected dividend yield	0%

- *Stock price.* Prior to the Business Combination, the stock price was determined by third party valuations of the Company's common stock.
- *Expected stock-price volatility.* The expected volatility is derived from the historical volatilities of comparable publicly traded companies within the Company's industry over a period approximately equal to the expected term. The comparable companies were utilized as the Company's stock does not have sufficient historical trading activity.
- *Expected term.* The expected term represents the period that the stock-based awards are expected to be outstanding. The Company's historical share option exercise experience does not provide a reasonable basis upon which to estimate an expected term due to a lack of sufficient data. Therefore, the Company estimates the expected term for employees by using the simplified method provided by the Securities and Exchange Commission. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options.
- *Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities approximately equal to the expected term.
- *Expected dividend yield.* The expected dividend is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on the Company's common stock.

The weighted-average grant date fair value of options granted during the year ended December 31, 2020 was $2.20. There were no options granted during the year ended December 31, 2021.

As of December 31, 2021, the Company had an aggregate of $37,690 of unrecognized share-based compensation cost, which is expected to be recognized over the weighted average period of 1.44 years.

Shares Reserved for Future Issuance

The following shares of common stock are reserved for future issuance:

	December 31, 2021
Stock options outstanding	4,444,068
Stock options available for future grant under 2021 Omnibus Incentive Plan	1,000,000
Warrants outstanding	21,090,873
Total shares of common stock reserved for future issuance	26,534,941

NOTE 10 - INCOME TAXES

Loss before provision for income taxes consisted of the following:

	December 31,	
	2021	2020
United States	$ (29,145,901)	$ (159,275)

The federal and state income tax provision (benefit), included in general and administrative expenses in the Consolidated Statement of Operations, is summarized as follows:

	December 31,	
	2021	**2020**
Current state provision	$ -	$ 1,600

The effective tax rate of the Company's provision (benefit) for income taxes differs from the federal statutory rate for the years ended December 31, 2021 and 2020 as follows:

	December 31,	
	2021	2020
Income (benefit) taxes at statutory rates	$ (6,120,640)	$ (33,448)
State income tax, net of federal benefit	(131,962)	47,340
Warrants and convertible debt	1,620,341	12,776
Nondeductible executive compensation	480,248	-
Stock based compensation	(278,940)	-
Share subscription facility transaction costs	2,664,850	-
Research and development tax credits	(501,451)	-
Change in tax rates	371,784	-
Other	(139,213)	405

Change in valuation allowance	2,034,983	(27,073)
Total	$ -	$ -

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

The Company's deferred tax assets were comprised of the following as of December 31, 2021 and 2020:

	As of December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss tax carryforwards	$ 25,068,127	$ 23,332,247
Tax credits	3,164,799	2,663,350
Stock-based compensation	915,675	1,798,263
Other	687,422	89,880
	29,836,023	27,883,740
Valuation allowance	(29,830,534)	(27,795,550)
Total deferred tax assets	5,489	88,190
Deferred tax liabilities:		
Convertible notes: embedded derivatives	-	(81,603)
Other	(5,489)	(6,587)
Total deferred tax liabilities	(5,489)	(88,190)
Net deferred tax assets	$ -	$ -

As of December 31, 2021, the Company had federal, California and other state net operating loss (NOL) carryforwards of $95.9 million, $69.7 million and $0.4 million, respectively, net of the NOLs that will expire due to Internal Revenue Code (IRC) Section 382 limitations. The federal net operating losses generated in 2018 and after of $13.5 million will carryforward indefinitely and be available to offset up to 80% of future taxable income each year, subject to certain modifications made by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") enacted in 2020. The federal net operating losses generated prior to 2018 of $82.4 million will begin to expire in 2026 unless previously utilized. The California and other state NOL carryforwards will begin to expire in 2028 and 2041, respectively, unless previously utilized.

In addition, as of December 31, 2021, the Company had federal and state research and development (R&D) tax credit carryforwards of $3.0 million and $1.5 million, respectively. The federal tax credit carryforwards will begin to expire in 2024 unless previously utilized. The California research tax credits do not expire.

Pursuant to the IRC Sections 382 and 383, annual use of the Company's NOL and R&D credit carryforwards may be limited in the event that a cumulative change in ownership of more than 50% occurs within a three-year period. Although the Company has not completed a recent IRC Section 382/383 analysis, regarding the limitation of NOL and R&D credit carryforwards, the Company estimates that approximately $1.5 million of tax benefits related to NOL and R&D carryforwards acquired in 2015 will expire unused. Accordingly, the related NOL and R&D credit carryforwards have been removed from deferred tax assets accompanied by a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, limitations created by current and future ownership changes, if any, related to the Company's operations in the United States will not impact its effective tax rate. Any additional ownership changes may further limit the ability to use the NOL and R&D credit carryforwards.

On March 27, 2020, the CARES Act was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits federal NOL carryforwards and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows federal NOLs incurred in 2019, 2020 and 2021 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. Due to the Company's history of net operating losses, the CARES Act is not expected to have a material impact on the Company's financial statements.

The following table summarizes the activity related to the Company's unrecognized tax benefits:

	Year ending December 31,	
	2021	2020
Balance at beginning of year	$ 968,445	$ 929,990
Increases (decreases) related to current year tax positions	171,977	38,455
Increases (decreases) related to prior year tax positions	(5,243)	-
Expiration of the statute of limitations for the assessment of taxes	-	-
Other	-	-
Balance at end of year	$ 1,135,179	$ 968,445

As of December 31, 2021 and 2020, the Company had unrecognized tax benefits of $1.1 million and $1.0 million, respectively. Due to the existence of the valuation allowance, none of the unrecognized tax benefits would affect the effective tax rate. The Company's policy is to recognize interest and penalties from uncertain tax positions in income tax expense. The Company did not record any interest or penalties for the years ended December 31, 2021 or 2020 and had no accrued interest on the consolidated balance sheets as of December 31, 2021 or 2020. The Company does not anticipate that the total amount of unrecognized tax benefits will significantly increase or decrease within twelve months of the reporting date.

The Company and its subsidiaries are subject to U.S. federal income tax as well as income tax in multiple state jurisdictions. With few exceptions, the Company is no longer subject to United States federal income tax examinations for years before 2018 and state and local income tax examinations before 2017. However, to the extent allowed by law, the tax authorities may have the right to examine prior periods where net operating losses were generated and carried forward, and make adjustments up to the amount of the NOL carryforward. The Company is not currently under examination by the Internal Revenue Service or any state or local tax authority.

NOTE 11 - RELATED PARTIES

The Company paid cash compensation during the year ended December 31, 2021 and 2020 of $30,909 and $129,890, respectively, to the Chief Executive Officer through a separate operating company with which the Chief Executive Officer is affiliated. As of December 31, 2021 and 2020, the Company owed $0 and $12,989, respectively, in accounts payable to the separate operating company.

The Company issued a series of convertible notes to the Chairman of the Board as described in Note 7, which totaled $2.5 million as of December 31, 2020. All outstanding notes and accrued interest converted into common stock upon the closing of the Business Combination on June 30, 2021.

As of December 31, 2021 and 2020, the Company had promissory notes outstanding which totaled $0 and $100,000, respectively, to three members of the board of directors, including the Chief Executive Officer and Chairman of the Board, as described in Note 7.

NOTE 12 - SUBSEQUENT EVENTS

On January 26, 2022, two proposals were approved at a special meeting of stockholders. The first proposal approved the issuance of shares of common stock upon the conversion of the 2021 Notes, as discussed in Note 7, and the exercise of the related warrants, in order to comply with certain Nasdaq rules. The second proposal approved an Amended and Restated 2021 Omnibus Incentive Plan, including an additional 3,000,000 shares available for future grant. Following this approval, the Company has granted a total of 1,986,000 stock options and 927,358 restricted stock units under the Plan to employees and consultants in 2022.

In the first quarter of 2022, the Company has issued 4,708,525 shares of common stock in repayment of $6.4 million in monthly redemptions of the 2021 Notes, as discussed in Note 7.

Exhibit Index

No.	Description of Exhibit
2.1†	Agreement and Plan of Merger, dated January 31, 2021, by and among Leisure Acquisition Corp., Ensysce Biosciences, Inc. and EB Merger Sub, Inc. (incorporated by reference to Exhibit 2.1 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
3.1	Third Amended and Restated Certificate of Incorporation of Ensysce Biosciences, Inc. (incorporated by reference to Exhibit 3.1 filed with the registrant's Current Report on Form 8-K on July 7, 2021).
3.2	Amended and Restated Bylaws of Ensysce Biosciences, Inc. (incorporated by reference to Exhibit 3.2 filed with the registrant's Current Report on Form 8-K on July 7, 2021).
4.1	Warrant Agreement, dated December 1, 2017, between the Leisure Acquisition Corp. and Continental Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.1 filed with the registrant's Current Report on Form 8-K on December 5, 2017).
4.2	Common Stock Purchase Warrant in the amount of 100,000 shares of common stock of Ensysce Biosciences, Inc. dated as of August 13, 2019 (incorporated by reference to Exhibit 4.5 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
4.3	Investor Rights Agreement between Ensysce Biosciences, Inc. and the Investors listed on the signature pages thereto dated as of May 11, 2018 (incorporated by reference to Exhibit 4.6 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
4.4	Warrant Certificate issued to Gateway Casinos & Entertainment Limited (incorporated by reference to Exhibit 4.7 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
4.5	Form of Warrant Certificate issued to previous holders of Private Placement Warrants and other private warrants (incorporated by reference to Exhibit 4.8 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
4.6	Form of Senior Secured Convertible Promissory Note issued by the Company pursuant to and in accordance with the Securities Purchase Agreement (incorporated by reference to Exhibit 4.6 filed with the registrant's Current Report on Form 8-K initially filed on September 27, 2021).
4.7	Form of Common Stock Purchase Warrant to be issued by the Company pursuant to and in accordance with the Securities Purchase Agreement (incorporated by reference to Exhibit 4.7 filed with the registrant's Current Report on Form 8-K initially filed on September 27, 2021).
10.1	Registration Rights Agreement, dated December 1, 2017, among Leisure Acquisition Corp. and certain securityholders (incorporated by reference to Exhibit 10.2 filed with the registrant's Current Report on Form 8-K on December 5, 2017).
10.2	Warrant Purchase Agreement, dated December 1, 2017, between Leisure Acquisition Corp. and certain security holders (incorporated by reference to Exhibit 10.3 filed with the registrant's Current Report on Form 8-K on December 5, 2017).
10.3(a)	Administrative Services Agreement, dated December 1, 2017, between Leisure Acquisition Corp. and Hydra Management, LLC (incorporated by reference to Exhibit 10.4 filed with the registrant's Current Report on Form 8-K on December 5, 2017).
10.3(b)	Amendment to the Administrative Services Agreement, dated August 7, 2020, between Leisure Acquisition Corp. and Hydra Management, LLC (incorporated by reference to Exhibit 10.1 filed with the registrant's Quarterly Report on Form 10-Q on November 9, 2020).
10.3(c)	Expense Advancement Agreement, dated December 1, 2017, between Leisure Acquisition Corp., HG Vora Special Opportunities Master Fund, Ltd., Hydra Management, LLC and Matthews Lane Capital Partners LLC (incorporated by reference to Exhibit 10.5 filed with the registrant's Current Report on Form 8-K on December 5, 2017).
10.4(a)	Amendment to Expense Advancement Agreement, dated June 29, 2020 (incorporated by reference to Exhibit 10.2 filed with the registrant's Current Report on Form 8-K on June 30, 2020).
10.4(b)	Amendment No. 2 to Expense Advancement Agreement, dated October 26, 2020 (incorporated by reference to Exhibit 10.1 filed with the registrant's Current Report on Form 8-K on October 29, 2020).
10.4(c)	Amendment No. 3 to Expense Advancement Agreement, dated November 30, 2020 (incorporated by reference to Exhibit 10.2 filed with the registrant's Current Report on Form 8-K on November 30, 2020).
10.4(d)	Amendment No. 4 to Expense Advancement Agreement, dated February 23, 2021 (incorporated by reference to Exhibit 10.2 filed with the registrant's Current Report on Form 8-K on February 25, 2021).

10.4(e)	Form of Amended and Restated Promissory Note relating to Expense Advancement Agreement (incorporated by reference to Exhibit 10.1 filed with the registrant's Current Report on Form 8-K on February 25, 2021).
10.5(a)	Letter Agreement, dated December 1, 2017, among the Leisure Acquisition Corp., its officers, directors and securityholders (incorporated by reference to Exhibit 10.6 filed with the registrant's Current Report on Form 8-K on December 5, 2017).
10.5(b)	Amendment to Letter Agreement, dated December 5, 2019 (incorporated by reference to Exhibit 10.6(b) filed with the registrant's Annual Report on Form 10-K on March 10, 2020).
10.6	Contingent Forward Purchase Contract, dated December 1, 2017, between Leisure Acquisition Corp. and HG Vora Special Opportunities Master Fund, Ltd (incorporated by reference to Exhibit 10.7 filed with the registrant's Current Report on Form 8-K on December 5, 2017).
10.7(a)	Form of Director and Officer Indemnity Agreement (incorporated by reference to Exhibit 10.8 filed with the registrant's Registration Statement on Form S-1 (File No.333-221330) initially filed on November 3, 2017).
10.7(b)	Form of Indemnification Agreement executed by each of the Ensysce directors and executive officers (incorporated by reference to Exhibit 10.6 filed with the registrant's Form 10-Q initially filed on November 15, 2021).
10.8	Securities Subscription Agreement, dated September 11, 2017, between LACQ and HG Vora Special Opportunities Master Fund, Ltd (incorporated by reference to Exhibit 10.4 filed with the registrant's Registration Statement on Form S-1 (File No.333-221330) initially filed on November 3, 2017).

10.9	Securities Subscription Agreement, dated September 11, 2017, between the Leisure Acquisition Corp. and Hydra Management, LLC (incorporated by reference to Exhibit 10.5 filed with the registrant's Registration Statement on Form S-1 (File No.333-221330) initially filed on November 3, 2017).
10.10	Securities Subscription Agreement, dated September 11, 2017, between the Leisure Acquisition Corp. and Matthews Lane Capital Partners LLC (incorporated by reference to Exhibit 10.6 filed with the registrant's Registration Statement on Form S-1 (File No.333-221330) initially filed on November 3, 2017).
10.11	Exchange Agreement, dated June 7, 2021, between Leisure Acquisition Corp. and Gateway Casinos & Entertainment Limited (incorporated by reference to Exhibit 10.12(d) filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.12	Fee Waiver Letter, dated November 23, 2020 (incorporated by reference to Exhibit 10.3 filed with the registrant's Current Report on Form 8-K on November 30, 2020).
10.13	Fee Waiver Letter, dated January 31, 2021 (incorporated by reference to Exhibit 10.2 filed with the registrant's Current Report on Form 8-K on February 2, 2021).
10.14	Warrant Surrender Agreement, among MLCP GLL Funding LLC, Hydra LAC, LLC, and Leisure Acquisition Corp., dated January 31, 2021 (incorporated by reference to Exhibit 10.1 filed with the registrant's Current Report on Form 8-K on February 2, 2021).
10.15	Form of Lock-up Agreement executed by each of the Ensysce's directors and executive officers (incorporated by reference to Exhibit 10.16 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.16+	Executive Employment Agreement, by and between the Company and Dr. Lynn Kirkpatrick, dated September 14, 2021 (incorporated by reference to Exhibit 10.44 filed with the registrant's Amendment Number 1 to its Registration Statement on Form S-1 (File No.333-260478) filed on October 29, 2021).
10.17	Agreement and Plan of Merger by and among the Signature Therapeutics, Inc., Signature Acquisition Corp. and the Company dated December 28, 2015 (incorporated by reference to Exhibit 10.21 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.18+	Employment Offer Letter to Richard Wright dated July 31, 2017 (incorporated by reference to Exhibit 10.24 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.19+	Executive Employment Agreement, by and between the Company and Geoffrey Birkett, dated August 21, 2021 (incorporated by reference to Exhibit 10.45 filed with the registrant's Amendment Number 1 to its Registration Statement on Form S-1 (File No.333-260478) filed on October 29, 2021)
10.20+	Employment Agreement between the Company and David Humphrey dated February 11, 2021 (incorporated by reference to Exhibit 10.26 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).

10.21+	Amendment to Offer Letter between the Company and David Humphrey dated February 23, 2021 (incorporated by reference to Exhibit 10.27 filed with the the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.22*+	Amended and Restated 2021 Omnibus Incentive Plan
10.22(a)*+	Amended and Restated 2021 Omnibus Incentive Plan Form of Stock Option Grant Notice and Award Agreement
10.23	Share Purchase Agreement between the Company, GEM Global Yield LLC SCS and GEM Yield Bahamas Limited dated as of December 29, 2020, including a Registration Rights Agreement between the same parties and dated as of the same date and form of Warrant to Purchase Common Shares of Ensysce Biosciences, Inc. issued by the Company to GEM Yield Bahamas Limited (incorporated by reference to Exhibit 10.29 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.24†	Technology Transfer Agreement by and among the Company, Covistat, Inc., Mucokinetica, Ltd., Roderick Hall and Peter Cole dated August 5, 2020 (incorporated by reference to Exhibit 10.30 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.25†+	Consulting Agreement between Roderick Hall and Covistat, Inc. dated August 5, 2020 (incorporated by reference to Exhibit 10.31 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.26†+	Consulting Agreement between Peter Cole and Covistat, Inc. dated August 5, 2020 (incorporated by reference to Exhibit 10.32 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.27	Manufacturing Agreement between Recro Gaineville LLC and the Company dated September 11, 2019 (incorporated by reference to Exhibit 10.35 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.28(a)	Form of Exchange Agreement between Leisure Acquisition Corp. and the holders of Private Placement Warrants (incorporated by reference to Exhibit 10.36(a) filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.28(b)	Form of Exchange Agreement to be entered into by the Company with each of the Sponsors and the Strategic Investor (incorporated by reference to Exhibit 10.36(b) filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.29	10.0% Convertible Promissory Note issued by the Company to Feliciano Global Enterprises Inc. on January 28, 2021 (incorporated by reference to Exhibit 10.37 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.30(a)	Email Agreement, dated January 31, 2021, between the Company and DelMorgan Group LLC (incorporated by reference to Exhibit 10.38(a) filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.30(b)	First Amendment to the Email Agreement, dated June 7, 2021, between the Company and DelMorgan Group LLC (incorporated by reference to Exhibit 10.38(b) filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.30(c)*	Settlement Agreement and Mutual General Release among the Company, Dr. Lynn Kirkpatrick, DelMorgan Group LLC and Globalist Capital LLC, dated August 3, 2021.
10.31(a)	Engagement Agreement with David L. Kovacs (a portion of Appendix B to the exhibit has been omitted)(incorporated by reference to Exhibit 10.37 filed with Ensysce Biosciences, Inc.'s Registration Statement on Form S-1 (File No.333-258609) initially filed on August 9, 2021.
10.31(b)*	Stock Option Grant Notice and Award Agreement granted February 14, 2022 to David L. Kovacs
10.32(a)	Engagement Agreement with Mercury FundingCo, LLC (a portion of Appendix B to the exhibit has been omitted) (incorporated by reference to Exhibit 10.38 filed with Ensysce Biosciences, Inc.'s Registration Statement on Form S-1 (File No.333-258609) initially filed on August 9, 2021).
10.32(b)*	Stock Option Grant Notice and Award Agreement granted February 14, 2022 to David Tanzer.
10.33(a)†	Securities Purchase Agreement, dated September 24, 2021 by and among the Company and the purchasers signatory thereto (incorporated by reference to Exhibit 10.1 filed with the registrant's Current Report on Form 8-K initially filed on September 27, 2021).
10.33(b)	Registration Rights Agreement, dated September 24, 2021, by and among the Company and the parties signatory thereto (incorporated by reference to Exhibit 10.2 filed with the registrant's Current Report on Form 8-K initially filed on September 27, 2021).
10.33(c)	Subsidiary Guarantee, dated September 24, 2021, by and among the Company and the purchasers signatory thereto (incorporated by reference to Exhibit 10.3 filed with the registrant's Current Report on Form 8-K initially filed on September 27, 2021).

10.33(d)†	Security Agreement, dated September 24, 2021, by and among the Company, EBI OpCo, Inc., Covistat, Inc. and the other parties signatory thereto (incorporated by reference to Exhibit 10.4 filed with the registrant's Current Report on Form 8-K initially filed on September 27, 2021).
10.33(e)	Patent Security Agreement, dated September 24, 2021, by and among the Company, EBI OpCo, Inc., Covistat, Inc. and the other parties signatory thereto (incorporated by reference to Exhibit 10.5 filed with the registrant's Current Report on Form 8-K initially filed on September 27, 2021).
10.33(f)	Letter Agreement, dated December 27, 2021, by and among the Company and the parties signatory thereto (incorporated by reference to Exhibit 10.6 filed with the registrant's Current Report on Form 8-K initially filed on December 27, 2021).
10.33(g)	Second Letter Agreement, dated January 16, 2022, by and among the Company and the parties signatory thereto (incorporated by reference to Exhibit 10.7 filed with the registrant's Current Report on Form 8-K initially filed on January 18, 2022).
21.1*	List of Subsidiaries

23.1*	Consent of Mayer Hoffman McCann P.C.
31.1*++	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rules 13a-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*++	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rules 13a-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*++	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*++	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(101)	Interactive Data File
(104)	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

* Filed herewith.

† Certain schedules (or similar attachments) to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5) or 601(b)(2), as applicable. The registrant agrees to furnish supplementally a copy of all omitted schedules to the Securities and Exchange Commission upon its request.

\+ Denotes compensatory plans or arrangements or management contracts.

++ This certificate accompanies this report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by Ensysce for purposes of Section 18 or any other provisions of the Exchange Act.

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in San Diego, State of California, on March 31, 2022.

ENSYSCE BIOSCIENCES, INC.

By: */s/ Dr. Lynn Kirkpatrick*
Name: Dr. Lynn Kirkpatrick
Title: President, Chief Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities indicated on March 31, 2022.

Name	Title
By: */s/ Dr. Lynn Kirkpatrick* Dr. Lynn Kirkpatrick	President, Chief Executive Officer and Director (Principal Executive Officer)
By: */s/ David Humphrey* David Humphrey	Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)
By: */s/ Andrew Benton* Andrew Benton	Director
By: */s/ William Chang* William Chang	Director
By: */s/ Bob Gower* Bob Gower	Director and Chairman of the Board
By: */s/ Adam Levin* Adam Levin	Director
By: */s/ Steve Martin* Steve Martin	Director
By: */s/ Lee Rauch* Lee Rauch	Director
By: */s/ Curtis Rosebraugh* Curtis Rosebraugh	Director

Exhibit 10.22

ENSYSCE BIOSCIENCES, INC.
AMENDED AND RESTATED 2021 OMNIBUS INCENTIVE PLAN

ARTICLE I

PURPOSE

The purpose of the Ensysce Biosciences, Inc. Amended and Restated 2021 Omnibus Incentive Plan (the "Plan") is to enhance the profitability and value of Ensysce Biosciences, Inc. (the "Company") for the benefit of its stockholders by enabling the Company to offer employees, directors and other service providers of the Company and its Affiliates, stock and stock-based incentive awards, to create a means to raise the level of stock ownership by, employees, directors and service providers in order to attract, retain and reward such individuals and strengthen the mutuality of interests between such individuals and the Company's stockholders. The Plan is effective as of the date set forth in Article XIV.

ARTICLE II

DEFINITIONS

For purposes of the Plan, the following terms shall have the following meanings:

2.1 "Acquisition Event" shall mean a merger or consolidation in which the Company is not the surviving entity, any transaction that results in the acquisition of all or substantially all of the Company's outstanding Common Stock by a single person or entity or by a group of persons and/or entities acting in concert, or the sale or transfer of all or substantially all of the Company's assets.

2.2 "Affiliate" shall mean other than the Company, (i) any corporation in an unbroken chain of corporations beginning with the Company, or in the event the Company is a Subsidiary, beginning with the Company's Parent, which owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain; (ii) any corporation, trade or business (including, without limitation, a partnership or limited liability company) which is controlled fifty percent (50%) or more (whether by ownership of stock, assets or an equivalent ownership interest or voting interest) by the Company and/or its Affiliates; or (iii) any other entity, approved by the Committee as an Affiliate under the Plan, in which the Company or any of its Affiliates has a material equity interest.

2.3 "Appreciation Award" shall mean any Award under the Plan of any Stock Option or Other Stock-Based Award, provided that such Other Stock-Based Award is based on the appreciation in value of a share of Common Stock in excess of an amount equal to at least the Fair Market Value of the Common Stock on the date such Other Stock-Based Award is granted.

2.4 "Award" shall mean any award under the Plan of Stock Options, Restricted Stock and Other Stock-Based Awards. All Awards shall be confirmed by, and subject to the terms of, a written agreement executed by the Company and the Participant or in the discretion of the Committee, a grant letter from the Company.

2.5 "Board" shall mean the Board of Directors of the Company.

2.6 "Cause" means, with respect to a Participant's Termination of Employment or Termination of Consultancy: (a) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Company or an Affiliate and the Participant at the time of grant of the Award that defines "cause" (or words of like import), as defined under such agreement; and (b) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Company or an Affiliate and the Participant at the time of grant of the Award (or where such an agreement exists but does not define "cause" (or words of like import)), termination due to a Participant's commission of a fraud or felony in connection with his or her duties as an employee or other service provider of the Company or an Affiliate, willful misconduct or any act of disloyalty, dishonesty, fraud, breach of trust or confidentiality as to the Company or an Affiliate, or any other act which is intended to cause or may reasonably be expected to cause economic or reputational injury to the Company or an Affiliate. With respect to a Participant's Termination of Directorship, "Cause" shall mean an act or failure to act that constitutes cause for removal of a director under applicable Delaware law.

2.7 "Change in Control" shall have the meaning set forth in Section 10.2.

2.8 "Code" shall mean the Internal Revenue Code of 1986, as amended.

2.9 "Committee" shall mean a committee or subcommittee of the Board (or an authorized committee thereof) appointed from time to time by the Board (or such authorized committee thereof), which committee or subcommittee shall consist of not less than two individuals, (i) each of whom is an "independent director" as defined under NASDAQ Listing Rule 5605(a)(2) or such other applicable stock exchange rule and (ii) to the extent required by Rule 16b-3, at least two of whom are "non-employee directors" as defined in Rule 16b-3. Notwithstanding the foregoing, if and to the extent that no Committee exists which has the authority to administer the Plan, the functions of the Committee shall be exercised by the Board. If for any reason the appointed Committee does not meet the requirements of Rule 16b-3, such noncompliance shall not affect the validity of the awards, grants, interpretations or other actions of the Committee. Any member of the Committee who does not meet the "non-employee director" standard as defined in Rule 16b-3 is required to abstain from the actions of the Committee, as the Committee may determine, in order to comply with Rule 16b-3. The Committee may also establish a subcommittee of the Committee that is intended to qualify as a committee consisting solely of two or more "non-employee directors," and may delegate to such subcommittee all approvals, certifications and administrative and other determinations with respect to compensation intended to be exempt under Rule 16b-3.

2.10 "Common Stock" shall mean subject to Article IV hereof, the common stock, $.01 par value per share, of the Company.

2.11 "Company" shall mean Ensysce Biosciences, Inc., a Delaware corporation, and any successors and assigns.

2.12 "Company Stock Plans" shall mean the Ensysce Biosciences, Inc. 2004 Stock Incentive Plan, 2008 Stock Incentive Plan, 2016 Stock Incentive Plan and the 2019 Directors Plan.

2.13 "Consultant" shall mean any natural person who provides bona fide consulting or advisory services to the Company or its Affiliates pursuant to a written agreement, which are not in connection with the offer and sale of securities in a capital-raising transaction, and do not, directly or indirectly, promote or maintain a market for the Company's or its Affiliates' securities.

2.14 "Disability" shall mean, with respect to a Participant's Termination, the failure or inability of a Participant to perform substantially the usual duties and

obligations of such individual on behalf of the Company or its Affiliates for one hundred eighty (180) days during any two hundred seventy (270) day period because of any mental or physical incapacity, as determined by the Committee in its sole discretion. Notwithstanding the foregoing, for Awards under the Plan that provide for payments that are triggered upon a Disability and that constitute "non-qualified deferred compensation" pursuant to Section 409A of the Code, Disability shall mean that a Participant is disabled under Section 409A(a)(2)(C)(i) of the Code.

2.15 "Eligible Employees" shall mean each employee of the Company and its Affiliates who are eligible pursuant to Article V to be granted Awards under the Plan.

2.16 "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended and all rules and regulations promulgated thereunder. Any reference to any section of the Exchange Act shall also be a reference to any successor provision.

2.17 "Exercisable Awards" shall mean any Award under the Plan of any Stock Option and any Other Stock Based Award that provides for a Participant-elected exercise.

2.18 "Fair Market Value" for purposes of the Plan, unless otherwise required by any applicable provision of the Code or any regulations issued thereunder, shall mean, as of any applicable date, the closing price of a share of Common Stock on the immediately preceding date, (i) as reported by the principal national securities exchange in the United States on which it is then traded or The Nasdaq Stock Market or (ii) if not traded on any such national securities exchange or The Nasdaq Stock Market, as quoted on an automated quotation system sponsored by the Financial Industry Regulatory Authority, or if the Common Stock shall not have been reported or quoted on such date, on the first day prior thereto on which the Common Stock was reported or quoted; provided that, to the extent consistent with the requirements of Section 422 or 409A of the Code, as applicable, the Committee may modify the definition of Fair Market Value to reflect any changes in the trading practices of any exchange on which the Common Stock is listed or traded. For purposes of the grant of any Award, the applicable date shall be the date as of which the Award is granted; provided that such date shall in no event be prior to the date the Committee makes the determination to grant the Award. For purposes of the exercise of any Award, the applicable date shall be the date a notice of exercise is received by the Committee or, if not a day on which the applicable market is open, the next day that it is open. Notwithstanding the foregoing, if the Committee determines that such mean does not properly reflect the fair market value of the Common Stock, the Fair Market Value shall be determined by the Committee using such method as it deems reasonable and consistent with the applicable requirements of the Code and the regulations issued thereunder, including without limitation the requirements of Section 422 or 409A of the Code, as applicable.

2.19 "Incentive Stock Option" shall mean any Stock Option awarded to an Eligible Employee under the Plan intended to be and designated as an "Incentive Stock Option" within the meaning of Section 422 of the Code.

2.20 "Non-Employee Director" shall mean a director of the Company or any of its Affiliates who is not an active employee of the Company or an Affiliate.

2.21 "Non-Qualified Stock Option" shall mean any Stock Option awarded under the Plan that is not an Incentive Stock Option.

2.22 "Other Stock-Based Award" shall mean an Award under Article VIII of the Plan that is valued in whole or in part by reference to, or is payable in or otherwise based on, Common Stock, including, without limitation, an Award valued by reference to an Affiliate.

2.23 "Parent" shall mean any parent corporation of the Company within the meaning of Section 424(e) of the Code.

2.24 "Participant" shall mean an Eligible Employee, Non-Employee Director or Consultant to whom an Award has been made pursuant to the Plan.

2.25 "Performance Goal" shall mean the performance goals described on Exhibit A.

2.26 "Restricted Stock" shall mean an award of Common Stock that is subject to Article VII.

2.27 "Restriction Period" shall have the meaning set forth in Section 7.1.

2.28 "Rule 16b-3" shall mean Rule 16b-3 under Section 16(b) of the Exchange Act.

2.29 "Section 409A of the Code" shall mean the nonqualified deferred compensation rules under Section 409A of the Code and any applicable Treasury regulations thereunder.

2.30 "Securities Act" shall mean the Securities Act of 1933, as amended and all rules and regulations promulgated thereunder. Any reference to any section of the Securities Act shall also be a reference to any successor provision.

2.31 "Stock Option" shall mean any option to purchase shares of Common Stock granted to Eligible Employees, Non-Employee Directors or Consultants pursuant to Article VI.

2.32 "Subsidiary" shall mean any subsidiary corporation of the Company within the meaning of Section 424(f) of the Code.

2.33 "Ten Percent Shareholder" shall mean a person owning stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, its Subsidiaries or its Parent.

2.34 "Termination" shall mean a Termination of Consultancy, Termination of Directorship or Termination of Employment, as applicable.

2.35 "Termination of Consultancy" shall mean, subject to the next sentence: (a) that the Consultant is no longer acting as a consultant to the Company or an Affiliate; or (b) when an entity which is retaining a Participant as a Consultant ceases to be an Affiliate unless the Participant otherwise is, or thereupon becomes, a Consultant to the Company or another Affiliate at the time the entity ceases to be an Affiliate. In the event that a Consultant becomes an Eligible Employee or a Non-Employee Director upon the termination of his or her consultancy, unless otherwise determined by the Committee, in its sole discretion, no Termination of Consultancy shall be deemed to occur until such time as such Consultant is no longer a Consultant, an Eligible Employee or a Non-Employee Director. Notwithstanding the foregoing, the Committee may otherwise define Termination of Consultancy in the Award agreement or, if no rights of a Participant are reduced, may otherwise define Termination of Consultancy thereafter.

2.36 "Termination of Directorship" shall mean, subject to the next sentence, with respect to a Non-Employee Director, that the Non-Employee Director is no longer serving as a director of the Company or an Affiliate. In the event that a Non-Employee Director becomes a Consultant or an Eligible Employee upon the termination of his or her directorship, unless otherwise determined by the Committee, in its sole discretion, no Termination of Directorship shall be deemed to occur until such time as such Non-Employee Director is no longer an Eligible Employee, a Consultant or a Non-Employee Director. The Committee may otherwise define Termination of Directorship in the Award agreement or, if no rights of a Participant are reduced, may otherwise define Termination of Directorship thereafter.

2.37 "Termination of Employment" shall mean, subject to the next sentence: (a) a termination of service (for reasons other than a military or personal leave of absence granted by the Company) of a Participant from the Company and its Affiliates; or (b) an entity that is employing a Participant has ceased to be an Affiliate, unless the Participant thereupon becomes employed by the Company or another Affiliate. In the event that an Eligible Employee becomes a Consultant or a Non-Employee Director upon the termination of his or her employment, unless otherwise determined by the Committee, in its sole discretion, no Termination of Employment shall be deemed to occur until such time as such Eligible Employee is no longer an Eligible Employee, a Consultant or a Non-Employee Director. The Committee may otherwise define Termination of Employment in the Award agreement or, if no rights of a Participant are reduced, may otherwise define Termination of Employment thereafter.

2.38 "Transfer" or "Transferred" shall mean anticipate, alienate, attach, sell, assign, pledge, encumber, charge or otherwise transfer.

2.39 "409A Covered Award" shall mean an Award that constitutes "non-qualified deferred compensation" pursuant to Section 409A of the Code.

ARTICLE III

ADMINISTRATION

3.1 The Committee. The Plan shall be administered and interpreted by the Committee.

3.2 Awards. The Committee shall have full discretionary power and authority to grant, pursuant to the terms of the Plan, Awards to Eligible Employees, Consultants and Non-Employee Directors. In particular, the Committee shall have the authority:

(a) to select the Eligible Employees, Consultants and Non-Employee Directors to whom Awards may from time to time be granted hereunder;

(b) to determine whether and to what extent Awards, or any combination thereof, are to be granted hereunder to one or more Eligible Employees, Consultants and Non-Employee Directors;

(c) to determine the number of shares of Common Stock to be covered by each Award granted hereunder;

(d) to determine the terms and conditions, not inconsistent with the terms of the Plan, of any Award granted hereunder (including, but not limited to, the share price, any restriction or limitation, any vesting terms or schedule (including time-based and performance-based vesting conditions) or acceleration thereof, or any forfeiture restrictions or waiver thereof, regarding any Award, and the shares of Common Stock relating thereto, based on such factors, if any, as the Committee shall determine, in its sole discretion);

(e) to determine the effect on a Participant's Award(s) granted under the Plan of a Participant's breach or violation of any restrictive covenants (including, without limitation, non-competition, non-solicitation and confidential information) set forth in a written agreement between the Participant and the Company or any of its Affiliates, including an Award agreement under the Plan;

(f) to determine whether and under what circumstances an Award may be settled in cash and/or Common Stock;

(g) to modify, extend or renew an Award, subject to Section 6.3(f) hereof and applicable law, including Code Section 409A;

(h) to determine whether a Stock Option is an Incentive Stock Option or Non-Qualified Stock Option; and;

(i) to determine whether to require an Eligible Employee, Consultant or Non-Employee Director, as a condition of the granting of an Award, not to sell or otherwise dispose of shares acquired pursuant to the exercise of a Stock Option for a period of time as determined by the Committee, in its sole discretion, following the date of the acquisition of such Stock Option.

3.3 Guidelines.

(a) Subject to Article XI hereof, the Committee shall have the authority to adopt, alter and repeal such administrative rules, guidelines and practices governing the Plan and perform all acts, including the delegation of its administrative responsibilities (to the extent permitted by applicable law and applicable stock exchange rules), as it shall, from time to time, deem advisable; to construe and interpret the terms and provisions of the Plan and any Award issued under the Plan (and any agreements relating thereto); and to otherwise supervise the administration of the Plan. The Committee may correct any defect, supply any omission or reconcile any inconsistency in the Plan or in any agreement relating thereto in the manner and to the extent it shall deem necessary to carry the Plan into effect. To the extent applicable, the Plan is intended to comply with the applicable requirements of Rule 16b-3 and shall be limited, construed and interpreted in a manner so as to comply therewith.

(b) Without limiting the foregoing, the Committee shall have the authority to establish special guidelines, provisions and procedures applicable to Awards granted to persons who are residing or employed in, or subject to, the taxes of, countries other than the United States to accommodate differences in applicable tax, securities or other local law. The Committee may adopt supplements or amendments to the Plan to reflect the specific requirements of local laws and procedures of non-United States jurisdictions without affecting the terms of the Plan as then in effect for any other purposes.

3.4 Decisions Final. Any decision, interpretation or other action made or taken in good faith by or at the direction of the Company, the Board or the Committee (or any of its members) arising out of or in connection with the Plan shall be within the absolute discretion of all and each of them, as the case may be, and shall be final, binding and conclusive on the Company and all employees and Participants and their respective heirs, executors, administrators, successors and assigns.

3.5 Procedures. If the Committee is appointed, the Board shall designate one of the members of the Committee as chairman and the Committee shall hold meetings, subject to the By-Laws of the Company, at such times and places as the Committee shall deem advisable, including, without limitation, by telephone conference or by written consent. A majority of the Committee members shall constitute a quorum. All determinations of the Committee shall be made by a majority of its members. Any decision or determination reduced to writing and signed by all the Committee members in accordance with the By-Laws of the Company, shall be fully effective as if it had been made by a vote at a meeting duly called and held. The Committee shall keep minutes of its meetings and shall make such rules and regulations for the conduct of its business as it shall deem advisable.

3.6 Designation of Consultants/Liability.

(a) The Committee may designate employees of the Company and professional advisors to assist the Committee in the administration of the Plan (to the extent permitted by applicable law and applicable exchange rules) and, subject to applicable law, may grant authority to officers to grant Awards or execute agreements or other documents on behalf of the Committee, provided that officer who has authority to grant Awards may not grant Awards to himself or herself.

(b) The Committee may employ such legal counsel, consultants and agents as it may deem desirable for the administration of the Plan and may rely upon any opinion received from any such counsel or consultant and any computation received from any such consultant or agent. Expenses incurred by the Committee or Board in the engagement of any such counsel, consultant or agent shall be paid by the Company. The Committee, its members and any person designated pursuant to paragraph (a) above shall not be liable for any action or determination made in good faith with respect to the Plan. To the maximum extent permitted by applicable law, no officer or former officer of the Company or member or former member of the Committee or of the Board shall be liable for any action or determination made in good faith with respect to the Plan or any Award granted under it. To the maximum extent permitted by applicable law and the Certificate of Incorporation and By-Laws of the Company and to the extent not covered by insurance directly insuring such person, each officer or former officer and member or former member of the Committee or of the Board shall be indemnified and held harmless by the Company against any cost or expense (including reasonable fees of counsel reasonably acceptable to the Company) or liability (including any sum paid in settlement of a claim with the approval of the Company), and advanced amounts necessary to pay the foregoing at the earliest time and to the fullest extent permitted, arising out of any act or omission to act in connection with the administration of the Plan, except to the extent arising out of such officer's or former officer's, member's or former member's own fraud or bad faith. Such indemnification shall be in addition to any rights of indemnification the employee, officer, director or member or former employee, officer, director or member may have under applicable law or under the Certificate of Incorporation or By-Laws of the Company or any Affiliate. Notwithstanding anything else herein, this indemnification will not apply to the actions or determinations made by an individual with regard to Awards granted to him or her under the Plan.

ARTICLE IV

SHARE AND OTHER LIMITATIONS

4.1 Shares.

(a) *General Limitation.*

(i) The aggregate number of shares of Common Stock that may be the subject of Awards under the Plan (subject to any increase or decrease pursuant to Section 4.2), is the sum of: (w) 4,444,068 shares underlying outstanding awards under the Company Stock Plans that have been converted into Awards under this Plan as of the Original Effective Date, (x) 1,000,000 additional shares reserved for issuance under the Plan as of the Original Effective Date, (y) 3,000,000 additional shares reserved for issuance under the Plan as of the Restatement Effective Date, and (z) an annual increase on January 1, 2023 and each anniversary of such date thereafter prior to the termination of the Plan, equal to the lesser of (A) 5% of the shares of Common Stock issued and outstanding on the last day of the immediately preceding fiscal year and (B) such smaller number of shares of Common Stock as determined by the Board, all of which shares may be either authorized and unissued Common Stock or Common Stock held in or acquired for the treasury of the Company or both. The maximum number of shares of Common Stock that may be issued pursuant to Stock Options intended to be Incentive Stock Options is 25,332,204. Following the Restatement Effective Date, any shares issued by the Company through the assumption or substitution of outstanding grants in connection with the acquisition of another entity shall not reduce the maximum number of shares available for delivery under the Plan.

(ii) If any Appreciation Award granted under the Plan expires, terminates or is canceled for any reason without having been exercised in full, the number of shares of Common Stock underlying such unexercised or repurchased Award shall again be available for the purposes of Awards under the Plan. If a share of Restricted Stock or a share of Common Stock underlying an Other Stock-Based Award that is not an Appreciation Award is forfeited for any reason, the number of forfeited shares of Common Stock comprising or underlying such Award shall again be available for the purposes of Awards under the Plan. Any Award settled in cash shall again be available for the purposes of Awards under the Plan.

(iii) Shares of common stock withheld in settlement of a tax withholding obligation associated with an Award, or in satisfaction of the exercise price payable upon exercise of an Appreciation Award, will again become available for grant under the Plan.

(b) *Non-Employee Director Individual Limitation.* The aggregate amount of equity and cash compensation (collectively "Compensation") payable to a Non-Employee Director with respect to a calendar year, whether under the Plan or otherwise, for services as a Non-Employee Director, shall not exceed $750,000; provided however, that such amount shall be $1,000,000 for the calendar year in which the applicable Non-Employee Director is initially elected or appointed to the Board (collectively, the "Director Limit"). Equity incentive awards shall be counted towards the Director Limit in the year in which they are granted, based on the grant date fair value of such awards for financial reporting purposes (but excluding the impact of estimated forfeitures related to service-based vesting provisions). Cash fees shall be counted towards the Director Limit in the year for which they are reported as compensation in the Company's director compensation disclosures pursuant to Item 402 of Regulation S-K under the Securities Act. The Director Limit shall not apply to (i) Compensation earned by a Non-Employee Director solely in his or her capacity as chairman of the Board or lead independent director; (ii) Compensation earned with respect to services a Non-Employee Director provides in a capacity other than as a Non-Employee Director, such as an advisor or consultant to the Company; and (iii) Compensation awarded by the Board to a Non-Employee Director in extraordinary circumstances, as determined by the Board in its discretion, in each case provided that the Non-Employee Director receiving such additional Compensation does not participate in the decision to award such Compensation.

4.2 Changes.

(a) The existence of the Plan and the Awards granted hereunder shall not affect in any way the right or power of the Board or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, any merger or consolidation of the Company or its Affiliates, any issue of bonds, debentures, preferred or prior preference stock ahead of or affecting Common Stock, the dissolution or liquidation of the Company or its Affiliates, any sale or transfer of all or part of its assets or business or any other corporate act or proceeding.

(b) In the event of any such change in the capital structure or business of the Company by reason of any stock dividend or distribution, stock split or reverse stock split, spin-off, recapitalization, reorganization, merger, consolidation, split-up, combination or exchange of shares, non-cash distribution with respect to its outstanding Common Stock of capital stock other than Common Stock, reclassification of its capital stock, any sale or transfer of all or part of the Company's assets or business, or any similar change affecting the Company's capital structure or business and the Committee determines in good faith that an adjustment is necessary or appropriate under the Plan to reflect the change, then the aggregate number and kind of shares which thereafter may be issued under the Plan and the number and kind of shares or other property (including cash) to be issued upon exercise of an outstanding Exercisable Award or under Restricted Stock or an Other Stock-Based Award that is not an Exercisable Award granted under the Plan and the purchase price thereof shall be appropriately adjusted consistent with such change, and such other changes in the Awards may be made in such manner as the Committee may deem necessary or appropriate to reflect the change, and any such adjustment determined by the Committee in good faith shall be binding and conclusive on the Company and all Participants and employees and their respective heirs, executors, administrators, successors and assigns. Except as provided in this Section 4.2, a Participant shall have no rights by reason of any issue by the Company of stock of any class or securities convertible into stock of any class, any subdivision or consolidation of shares of stock of any class, the payment of any stock dividend, any other increase or decrease in the number of shares of stock of any class, any sale or transfer of all or part of the Company's assets or business or any other change affecting the Company's capital structure or business.

(c) Fractional shares of Common Stock resulting from any adjustment in Awards pursuant toSection 4.2(a) or (b) shall be aggregated until, and eliminated at,

the time of exercise or settlement by rounding-down to the nearest whole share. No fractional shares of Common Stock shall be issued under the Plan. No cash settlements shall be made with respect to fractional shares eliminated by founding. Notice of any adjustment shall be given by the Committee to each Participant whose Award has been adjusted and such adjustment (whether or not such notice is given) shall be effective and binding for all purposes of the Plan.

(d) Upon the occurrence of an Acquisition Event, then the Committee may, in its sole discretion, terminate all outstanding Exercisable Awards of Eligible Employees, Consultants or Non-Employee Directors effective as of the date of the Acquisition Event, by delivering notice of termination to each such Participant at least twenty (20) days prior to the date of consummation of the Acquisition Event; provided, that, unless otherwise determined by the Committee at or after the time of grant, during the period from the date on which such notice of termination is delivered to the consummation of the Acquisition Event, each Eligible Employee shall have the right to exercise in full all of his or her Exercisable Awards that are then outstanding (unless otherwise determined by the Committee, whether vested or not vested and without regard to any limitations on exercisability otherwise contained in the Exercisable Award) but contingent on the occurrence of the Acquisition Event, and, provided that, if the Acquisition Event does not take place within a specified period after giving such notice for any reason whatsoever, the notice and exercise shall be null and void. If an Acquisition Event occurs, to the extent the Committee does not terminate the outstanding Exercisable Award pursuant to this Section 4.2(d), then the provisions of Section 4.2(b) shall apply.

4.3 Minimum Purchase Price. Notwithstanding any provision of this Plan to the contrary, if authorized but previously unissued shares of Common Stock are issued under this Plan, such shares shall not be issued for a consideration which is less than as permitted under applicable law, which, to the extent permitted under applicable law, may include past services to the Company or its Affiliates.

ARTICLE V

ELIGIBILITY

5.1 General Eligibility. All Eligible Employees and all Consultants and Non-Employee Directors of the Company and its Affiliates shall be eligible for grants of Non-Qualified Stock Options, Restricted Stock, and Other Stock-Based Awards. Eligibility for the grant of Awards and actual participation in the Plan shall be determined by the Committee in its sole discretion. Notwithstanding anything herein to the contrary, no Stock Option under which a Participant may receive Common Stock may be granted under the Plan to an Eligible Employee, Consultant or Non-Employee Director of the Company or any of its Affiliates if such Common Stock does not constitute "service recipient stock" for purposes of Section 409A of the Code with respect to such Eligible Employee, Consultant or Non-Employee Director, unless such Stock Option is structured in a manner intended to comply with, or be exempt from, Section 409A of the Code.

5.2 Incentive Stock Options. Notwithstanding anything herein to the contrary, only Eligible Employees of the Company, its Subsidiaries and its Parent (if any) shall be eligible for grants of Incentive Stock Options under the Plan. Eligibility for the grant of an Incentive Stock Option and actual participation in the Plan shall be determined by the Committee in its sole discretion.

ARTICLE VI

STOCK OPTIONS

6.1 Options. Each Stock Option granted hereunder shall be one of two types: (i) an Incentive Stock Option intended to satisfy the requirements of Section 422 of the Code; or (ii) a Non-Qualified Stock Option.

6.2 Grants. Subject to the provisions of Article V, the Committee shall have the authority to grant to any Eligible Employee one or more Incentive Stock Options, Non-Qualified Stock Options or any combination thereof. To the extent that any Stock Option does not qualify as an Incentive Stock Option (whether because of its provisions or the time or manner of its exercise or otherwise), such Stock Option or the portion thereof which does not so qualify, shall constitute a Non-Qualified Stock Option. The Committee shall have the authority to grant any Consultant or Non-Employee Director one or more Non-Qualified Stock Options.

6.3 Terms of Options. Options granted under the Plan shall be subject to the following terms and conditions, and shall be in such form and contain such additional terms and conditions, not inconsistent with the terms of the Plan, as the Committee shall deem desirable:

(a) *Exercise Price*. The exercise price per share of Common Stock subject to a Stock Option shall be determined by the Committee at the time of grant, but shall not be less than 100% of the Fair Market Value of a Common Stock at the time of grant; provided, however, that if an Incentive Stock Option is granted to a Ten Percent Shareholder, the exercise price shall be no less than 110% of the Fair Market Value of a share of Common Stock.

(b) *Stock Option Term*. The term of each Stock Option shall be fixed by the Committee, but no Stock Option shall be exercisable more than ten (10) years after the date the Option is granted; provided, however, the term of an Incentive Stock Option granted to a Ten Percent Shareholder shall not exceed five (5) years.

(c) *Exercisability*. Stock Options shall be exercisable at such time or times and subject to such terms and conditions as shall be determined by the Committee at grant. The Committee may condition the exercisability of the options upon the attainment of specified performance targets (including, the Performance Goals specified in Exhibit A hereto) or such other factors as the Committee may determine, in its sole discretion. If the Committee provides, in its discretion, that any Stock Option is exercisable subject to certain limitations (including, without limitation, that it is exercisable only in installments or within certain time periods), the Committee may waive limitations on the exercisability at any time at or after grant in whole or in part (including, without limitation, waiver of the installment exercise provisions or acceleration of the time at which Stock Options may be exercised), based on such factors, if any, as the Committee shall determine, in its sole discretion provided, that, unless otherwise determined by the Committee at grant, the grant shall provide that as a condition of the exercise of a Stock Option, the Participant shall be required to certify at the time of exercise in a manner acceptable to the Company that the Participant is in compliance with the terms and conditions of the Plan.

(d) *Method of Exercise*. Subject to whatever installment exercise and waiting period provisions apply under subsection (c) above, to the extent vested, Stock Options may be exercised in whole or in part at any time during the Stock Option term, by giving written notice of exercise to the Company specifying the number of shares of Common Stock to be purchased accompanied by payment in full of the purchase price and any taxes required to be withheld in connection with such exercise. Payment of the purchase price for shares of Common Stock issued pursuant to the exercise of a Stock Option may be made as follows: (i) in cash or by check, bank draft or money order payable to the order of Company; (ii) through the delivery to the Company of shares of Common Stock owned by the Participant (and for which the Participant has good title free and clear of any liens and encumbrances) based on the Fair Market Value of the Common Stock on the payment date; (iii) solely to the extent permitted by applicable law, if the Common Stock is traded on a national securities exchange or quoted on a national quotation system sponsored by the Financial Industry Regulatory Authority, and the Committee authorizes, through a procedure established by the Committee whereby the Participant delivers irrevocable instructions to a broker reasonably acceptable to the Committee to deliver promptly to the Company an amount equal to the purchase price; (iv) on such other terms and conditions as may be acceptable to the Committee (which may include a reduction in the number of shares of Common Stock issuable upon exercise, based on the Fair Market Value of the Common Stock on the payment date) or (v) any combination of the foregoing. Payment for shares of Common Stock purchased pursuant to exercise of a Stock Option shall be made at the principal offices of the Company. For purposes of this Section, the date of issuance shall be the date upon which payment in full of the purchase price has been received by (or tendered to) the Company as provided herein. No shares of Common Stock shall be issued until payment, as provided herein, therefor has been made or provided for.

(e) *Incentive Stock Option Limitations.* To the extent that the aggregate Fair Market Value (determined as of the time of grant) of the Common Stock with respect to which Incentive Stock Options are exercisable for the first time by an Eligible Employee during any calendar year under the Plan and/or any other stock option plan of the Company, any Subsidiary or any Parent exceeds $100,000, such Stock Options shall be treated as Non-Qualified Stock Options. In addition, if an Eligible Employee does not remain employed by the Company, any Subsidiary or any Parent at all times from the time an Incentive Stock Option is granted until three (3) months prior to the date of exercise thereof (or such other period as required by applicable law), such Stock Option shall be treated as a Non-Qualified Stock Option. To the extent permitted by applicable law, should any provision of the Plan not be necessary in order for the Stock Options to qualify as Incentive Stock Options, or should any additional provisions be required, the Committee may amend the Plan accordingly, without the necessity of obtaining the approval of the stockholders of the Company.

(f) *Form, Modification, Extension and Renewal of Stock Options.* Subject to the terms and conditions and within the limitations of the Plan, a Stock Option shall be evidenced by such form of agreement as is approved by the Committee, and the Committee may (i) subject to the requirements of Section 409A of the Code, modify, extend or renew outstanding Stock Options granted under the Plan (provided that the rights of a Participant are not reduced without his or her consent and provided that such action does not extend the Stock Option beyond its stated term), and (ii) subject to applicable law and the requirements of the principal national securities exchange in the United States on which the Common Stock is then traded or The Nasdaq Stock Market, accept the surrender of outstanding Stock Options (up to the extent not theretofore exercised) and authorize the granting of new Stock Options in substitution therefor (to the extent not theretofore exercised). Notwithstanding the foregoing, an outstanding Stock Option may not be modified to reduce the exercise price thereof nor may a new Stock Option at a lower price be substituted for a surrendered Stock Option, (other than adjustments or substitutions in accordance with Section 4.2), unless such action is approved by the stockholders of the Company.

(g) *Other Terms and Conditions*. Stock Options may contain such other provisions, which shall not be inconsistent with any of the foregoing terms of the Plan, as the Committee shall deem appropriate; provided, however, that Stock Options shall not provide for the grant of the same number of Stock Options as the number of shares used to pay for the exercise price of Stock Options or shares used to pay withholding taxes (i.e., "reloads").

6.4 Termination. The following rules apply with regard to Stock Options upon the Termination of a Participant, unless otherwise determined by the Committee at grant or, if no rights of the Participant or in the case of his death his estate are reduced, thereafter.

(a) *Termination by Reason of Death or Disability.* If a Participant's Termination is by reason of death or Disability, any Stock Option held by such Participant may be exercised, to the extent vested and exercisable at the time of such Termination by reason of death or Disability, by the Participant (or, in the case of death, by the legal representative of the Participant's estate), at any time within a period of one (1) year from the date of such Termination due to death or Disability, but in no event beyond the expiration of the stated term of such Stock Option.

(b) *Termination Other than for Cause.* If a Participant's Termination is for any reason other than a Termination by the Company or its Affiliate for Cause, death or Disability, any Stock Option held by such Participant may be exercised, to the extent vested and exercisable at termination, by the Participant at any time within a period of ninety (90) days from the date of such termination, but in no event beyond the expiration of the stated term of such Stock Option.

(c) *Termination for Cause.* In the event the Participant's Termination is (i) for Cause or (ii) a voluntary termination within ninety (90) days after occurrence of an event which would be grounds for Termination by the Company or its Affiliate for Cause (without regard to any notice or cure period requirement), any Stock Option (whether or not then vested or exercisable) held by the Participant at the time of occurrence of the event which would be grounds for Termination by the Company or its Affiliate for Cause shall be deemed to have terminated and expired upon occurrence of the event which would be grounds for Termination by the Company or its Affiliate for Cause.

ARTICLE VII

RESTRICTED STOCK

7.1 Awards of Restricted Stock. Restricted Stock may be issued to all eligible Participants pursuant toArticle V of the Plan either alone or in addition to other Awards granted under the Plan. The Committee shall determine the eligible Participants to whom, and the time or times at which, grants of Restricted Stock will be made, the number of shares to be awarded, the purchase price (if any) to be paid by the Participant (subject to Section 7.2), the time or times at which such Awards may be subject to forfeiture (if any), the vesting schedule (if any) and rights to acceleration thereof, and all other terms and conditions of the Awards. The Committee may condition the grant or vesting of Restricted Stock upon the attainment of specified performance targets (including, the Performance Goals specified in Exhibit A hereto) or such other factors as the Committee may determine, in its sole discretion. Unless otherwise determined by the Committee, the Participant shall not be permitted to transfer shares of Restricted Stock awarded under the Plan during a period set by the Committee (if any) (the "Restriction Period") commencing with the date of such Award, as set forth in the applicable Award agreement.

7.2 Awards and Certificates. A Participant selected to receive Restricted Stock shall not have any rights with respect to such Award, unless and until such Participant has delivered a fully executed copy of the Award agreement evidencing the Award to the Company and has otherwise complied with the applicable terms and conditions of such Award. Further, such Award shall be subject to the following conditions:

(a) *Purchase Price.* The purchase price of Restricted Stock shall be determined by the Committee and may be zero, but shall not be less than as permitted under applicable law.

(b) *Acceptance*. Awards of Restricted Stock must be accepted within a period of sixty (60) days (or such shorter period as the Committee may specify at grant) after the grant date, by executing an Award agreement and by paying whatever price (if any) the Committee has designated thereunder.

(c) *Legend.* Each Participant receiving Restricted Stock shall be issued a stock certificate in respect of such shares of Restricted Stock, unless the Committee elects to use another system, such as book entries by the transfer agent, as evidencing ownership of Restricted Stock. Such certificate shall be registered in the name of such Participant, and shall bear an appropriate legend referring to the terms, conditions, and restrictions applicable to such Award, substantially in the following form:

"The anticipation, alienation, attachment, sale, transfer, assignment, pledge, encumbrance or charge of the shares of stock represented hereby are subject to the terms and conditions (including forfeiture) of the Ensysce Biosciences, Inc. (the "Company") Amended and Restated 2021 Omnibus Incentive Plan (the "Plan"), and an Award agreement entered into between the registered owner and the Company dated _____. Copies of such Plan and Award agreement are on file at the principal office of the Company."

(d) *Custody*. The Committee may require that any stock certificates evidencing such shares be held in custody by the Company until the restrictions thereon shall have lapsed, and that, as a condition of any Restricted Stock Award, the Participant shall have delivered a duly signed stock power, endorsed in blank, relating to the Common Stock covered by such Award.

(e) *Rights as Stockholder; Dividends.* Except as provided in this subsection and subsection (d) above and as otherwise determined by the Committee, the

Participant shall have, with respect to the shares of Restricted Stock, all of the rights of a holder of shares of Common Stock of the Company including, without limitation, the right to receive any dividends, the right to vote such shares and, subject to and conditioned upon the full vesting of shares of Restricted Stock, the right to tender such shares. Notwithstanding the foregoing, dividends or other distributions on shares of Restricted Stock shall be withheld, in each case, while the Restricted Stock is subject to restrictions and no dividends or other distributions payable thereunder shall be paid unless and until the shares of Restricted Stock to which they relate are no longer subject to a risk of forfeiture. Dividends and other distributions that are not paid currently shall be credited to bookkeeping accounts on the Company's records for purposes of the Plan and, except as otherwise determined by the Committee, shall not accrue interest. Such dividends and other distributions shall be paid to the Participant in the same form as paid on the Common Stock upon the lapse of the restrictions.

(f) *Lapse of Restrictions.* If and when the Restriction Period expires without a prior forfeiture of the Restricted Stock subject to such Restriction Period, the certificates for such shares shall be delivered to the Participant. All legends shall be removed from said certificates at the time of delivery to the Participant except as otherwise required by applicable law. Notwithstanding the foregoing, actual certificates shall not be issued to the extent that book entry recordkeeping is used.

(g) *Termination*. Unless otherwise determined by the Committee at grant or thereafter, upon a Termination for any reason during the relevant Restriction Period, all Restricted Stock still subject to restriction shall be forfeited.

ARTICLE VIII

OTHER STOCK-BASED AWARDS

8.1 Other Stock-Based Awards. The Committee, in its sole discretion, is authorized to grant to Eligible Employees, Consultants and Non-Employee Directors Other Stock-Based Awards that are payable in, valued in whole or in part by reference to, or otherwise based on or related to shares of Common Stock, including but not limited to, shares of Common Stock awarded purely as a bonus and not subject to any restrictions or conditions, shares of Common Stock in payment of the amounts due under an incentive or performance plan sponsored or maintained by the Company or an Affiliate, stock equivalent units, restricted stock units, deferred stock units, and Awards valued by reference to book value of shares of Common Stock. Other Stock-Based Awards may be granted alone, in addition to or in tandem with other Awards granted under the Plan.

Subject to the provisions of the Plan, the Committee shall, in its sole discretion, have authority to determine the Eligible Employees, Consultants and Non-Employee Directors of the Company and its Affiliates, to whom, and the time or times at which, such Awards shall be made, the number of shares of Common Stock to be awarded pursuant to such Awards, and all other conditions of the Awards. The Committee may also provide for the grant of Common Stock under such Awards upon the completion of a specified performance period.

The Committee may condition the grant or vesting of Other Stock-Based Awards upon the attainment of specified performance targets (including, the Performance Goals specified in Exhibit A attached hereto) or such other factors as the Committee may determine, in its sole discretion.

8.2 Terms and Conditions. Other Stock-Based Awards made pursuant to this Article VIII shall be subject to the following terms and conditions:

(a) *Non-Transferability*. Subject to the applicable provisions of the Award agreement and the Plan, shares of Common Stock subject to Awards made under this Article VIII may not be Transferred prior to the date on which the shares are issued, or, if later, the date on which any applicable restriction, performance or deferral period lapses.

(b) *Dividends*. Unless otherwise determined by the Committee at the time of Award, subject to the provisions of the Award agreement and the Plan, the recipient of an Award under this Article VIII shall not be entitled to receive, currently or on a deferred basis, dividends or dividend equivalents with respect to the number of shares of Common Stock covered by the Award.

(c) *Vesting*. Any Award under this Article VIII and any Common Stock covered by any such Award shall vest or be forfeited to the extent so provided in the Award agreement, as determined by the Committee, in its sole discretion.

(d) *Price*. Common Stock issued on a bonus basis under this Article VIII may be issued for no cash consideration; Common Stock purchased pursuant to a purchase right awarded under this Article VIII shall be priced, as determined by the Committee in its sole discretion. The exercise or base price per share of Common Stock subject to an Other Stock-Based Award that is an Appreciation Award shall be determined by the Committee at the time of grant, but shall not be less than 100% of the Fair Market Value of a Common Stock at the time of grant.

(e) *Payment.* Form of payment for the Other Stock-Based Award shall be specified in the Award agreement and may be in shares of Common Stock.

(f) *Appreciation Award Term.* The term of each Other Stock-Based Award that is an Appreciation Award shall be fixed by the Committee, but no Other Stock-Based Award that is an Appreciation Award shall be exercisable more than ten (10) years after the date the Award is granted.

ARTICLE IX

NON-TRANSFERABILITY

9.1 Non-Transferability. Except as provided in the last sentence of this Article IX, no Award shall be Transferred by the Participant otherwise than by will or by the laws of descent and distribution, all Stock Options shall be exercisable, during the Participant's lifetime, only by the Participant, no Award shall, except as otherwise specifically provided by law or herein, be Transferred in any manner, and any attempt to Transfer any such Award shall be void. No Award shall in any manner be liable for or subject to the debts, contracts, liabilities, engagements or torts of any person who shall be entitled to such Award, nor shall it be subject to attachment or legal process for or against such person. Notwithstanding the foregoing, the Committee may determine at the time of grant or thereafter that a Non-Qualified Stock Option that is otherwise not Transferable pursuant to this Article IX is Transferable, in whole or in part, to a "family member" as defined in Securities Act Form S-8 and under such conditions as specified by the Committee.

ARTICLE X

CHANGE IN CONTROL PROVISIONS

10.1 Benefits. In the event of a Change in Control of the Company, except as otherwise provided by the Committee upon the grant of an Award, Awards granted to Participants shall not automatically vest upon a Change in Control and upon the Change in Control a Participant's Awards may be treated in accordance with one of the following methods, as determined by the Committee in its sole discretion, and without the need for the consent of any Participant and without the need to treat each Award the same:

(a) Awards, whether or not then vested, may be continued, assumed, have new rights substituted therefor or be treated in accordance with Section 4.2(d) hereof, as determined by the Committee in its sole discretion, and restrictions to which any shares of Restricted Stock or any other Award granted prior to the Change in Control are subject shall not lapse upon a Change in Control and the Restricted Stock or other Award shall, where appropriate in the sole discretion of the Committee, receive the same distribution as other Common Stock on such terms as determined by the Committee; provided that, the Committee may, in its sole discretion, decide to award additional Restricted Stock or other Award in lieu of any cash distribution. Notwithstanding anything to the contrary herein, for purposes of Incentive Stock Options, any assumed or substituted Stock Option shall comply with the requirements of Treasury Regulation § 1.424-1 (and any amendments thereto).

(b) Unvested Awards or any unvested portion thereof may be cancelled with or without consideration.

(c) Awards may be canceled in exchange for an amount of cash equal to the Change in Control Price (as defined below) per share of Common Stock covered by such Awards), less, in the case of an Appreciation Award, the exercise price per share of Common Stock covered by such Award. The " Change in Control Price" means the price per share of Common Stock paid in the Change in Control transaction, subject to adjustment as determined by the Committee for any contingent purchase price, escrow obligations, indemnification obligations or other adjustments to the purchase price after the consummation of such Change in Control.

(d) The Committee may, in its sole discretion, provide for the cancellation of any Appreciation Awards without payment, if the Change in Control Price is equal to or less than the exercise price of such Appreciation Award.

Notwithstanding anything else herein to the contrary: (x) In the discretion of the Committee, any cash or substitute consideration payable upon cancellation of an Award may be subjected to (i) vesting terms substantially identical to those that applied to the cancelled Award immediately prior to the Change in Control, or (ii) earn-out, escrow, holdback or similar arrangements, to the extent such arrangements are applicable to any consideration paid to stockholders in connection with the Change in Control; and (y) in the case of any Award subject to Section 409A of the Code, the Committee shall only be permitted to take actions under this Section 10.1 to the extent that such actions would be consistent with the intended treatment of such Award under Section 409A of the Code. Furthermore, notwithstanding anything else herein, the Committee may, in its sole discretion, provide for accelerated vesting or lapse of restrictions, of an Award at any time.

10.2 Change in Control. A "Change in Control" shall be deemed to have occurred under any one or more of the following events:

(a) upon any "person" as such term is used in Sections 13(d) and 14(d) of the Exchange Act (other than the Company, any trustee or other fiduciary holding securities under any employee benefit plan of the Company, or any company owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of Common Stock of the Company), becoming the owner (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing thirty percent (30%) or more of the combined voting power of the Company's then outstanding securities;

(b) during any period of two (2) consecutive years (the "Board Measurement Period"), individuals who at the beginning of such period constitute the Board of Directors, and any new director (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in subsections 10.2(a), (c) or (d)) or a director whose initial assumption of office occurs as a result of either an actual or threatened election contest (as such term is used in Rule 14a-11 of Regulation 14A promulgated under the Exchange Act) or other actual or threatened solicitation of proxies or consents by or on behalf of a person other than the Board of Directors of the Company whose election by the Board of Directors or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds (the "Required Approval") of the directors then still in office who either were directors at the beginning of the Board Measurement Period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the Board of Directors;

(c) upon the consummation of a merger or consolidation of the Company with any other corporation, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the combined voting power of the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; provided, however, that a merger or consolidation effected to implement a recapitalization of the Company (or similar transaction) in which no person (other than those covered by the exceptions in (i) above) acquires more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities shall not constitute a Change in Control of the Company;

(d) upon approval by the stockholders of the Company of a plan of complete liquidation of the Company; or

(e) upon the consummation of a sale or disposition by the Company of all or substantially all of the Company's assets other than the sale or disposition of all or substantially all of the assets of the Company to a person or persons who beneficially own, directly or indirectly, at least fifty percent (50%) or more of the combined voting power of the outstanding voting securities of the Company at the time of the sale.

Notwithstanding anything in the Plan or an Award agreement to the contrary, to the extent necessary to comply with Section 409A of the Code, no event that, but for the application of this sentence, would be a Change in Control as defined in the Plan or the Award agreement, as applicable, shall be a Change in Control unless such event is also a "change in control event" as defined in Section 409A of the Code.

ARTICLE XI

TERMINATION OR AMENDMENT OF THE PLAN

11.1 Termination or Amendment. Notwithstanding any other provision of the Plan, the Board may at any time, and from time to time, amend, in whole or in part, any or all of the provisions of the Plan (including any amendment deemed necessary to ensure compliance with any regulatory requirement referred to in Article XIII or Section 409A of the Code), or suspend or terminate it entirely, retroactively or otherwise; provided, however, that, unless otherwise required by law or specifically provided herein, the rights of a Participant with respect to Awards granted prior to such amendment, suspension or termination, may not be impaired without the consent of such Participant and, provided further, without the approval of the stockholders of the Company in accordance with the laws of the State of Delaware and the exchange or system on which the Company's securities are then listed or traded, or to the extent applicable to Incentive Stock Options, Section 422 of the Code, no amendment may be made that would: (a) increase the aggregate number of shares of Common Stock that may be issued under the Plan (except in accordance with Section 4.2; (b) increase the maximum individual Participant limits under Section 4.1(b) (except in accordance with Section 4.2); (c) change the classification of individuals eligible to receive Awards under the Plan; (d) other than adjustments or substitutions in accordance with Section 4.2, amend the terms of outstanding Awards to reduce the exercise price of outstanding Exercisable Awards or to cancel outstanding Exercisable Awards (where prior to the reduction or cancellation the exercise price equals or exceeds the fair market value of the shares of Common Stock underlying such Awards) in exchange for cash, other Awards or Exercisable Awards with an exercise price that is less than the exercise price of the original Exercisable Award; (e) extend the maximum option period under Section 6.3; (vii) award any Exercisable Award in replacement of a canceled Exercisable Award with a higher exercise price, except in accordance with Section 6.3(f); or (f) require stockholder approval under Section 422 of the Code to the extent applicable to Incentive Stock Options.

In no event may the Plan be amended without the approval of the stockholders of the Company in accordance with the applicable laws of the State of Delaware to increase the aggregate number of shares of Common Stock that may be issued under the Plan or to make any other amendment that would require stockholder approval under the rules of any exchange or system on which the Company's securities are listed or traded at the request of the Company.

The Committee may amend the terms of any Award theretofore granted, prospectively or retroactively, but, subject to Article IV above or as otherwise specifically provided herein, no such amendment or other action by the Committee shall impair the rights of any holder without the holder's consent.

Notwithstanding anything herein to the contrary, the Board may amend the Plan or any Award agreement at any time without a Participant's consent to comply with applicable law including Section 409A of the Code.

ARTICLE XII

UNFUNDED PLAN

12.1 Unfunded Status of Plan. The Plan is an "unfunded" plan for incentive and deferred compensation. With respect to any payments as to which a Participant has a fixed and vested interest but which are not yet made to a Participant by the Company, nothing contained herein shall give any such Participant any rights that are greater than those of a general unsecured creditor of the Company.

ARTICLE XIII

GENERAL PROVISIONS

13.1 Legend. The Committee may require each person receiving shares of Common Stock pursuant to an Award under the Plan to represent to and agree with the Company in writing that the Participant is acquiring the shares without a view to distribution thereof. In addition to any legend required by the Plan, the certificates for such shares may include any legend which the Committee deems appropriate to reflect any restrictions on Transfer.

All certificates for shares of Common Stock delivered under the Plan shall be subject to such stop transfer orders and other restrictions as the Committee may deem advisable under the rules, regulations and other requirements of the Securities and Exchange Commission, any stock exchange upon which the Common Stock is then listed or any national securities exchange system upon whose system the Common Stock is then quoted, any applicable Federal or state securities law, and any applicable corporate law, and the Committee may cause a legend or legends to be put on any such certificates to make appropriate reference to such restrictions.

13.2 Other Plans. Nothing contained in the Plan shall prevent the Board from adopting other or additional compensation arrangements, subject to stockholder approval if such approval is required; and such arrangements may be either generally applicable or applicable only in specific cases.

13.3 No Right to Employment/Directorship/Consultancy. Neither the Plan nor the grant of any Award hereunder shall give any Participant or other employee, Consultant or Non-Employee Director any right with respect to continuance of employment, directorship or consultancy by the Company or any Affiliate, nor shall they be a limitation in any way on the right of the Company or any Affiliate by which an employee is employed or a Consultant or Non-Employee Director is retained to terminate his employment, consultancy or directorship at any time. Neither the Plan nor the grant of any Award hereunder shall impose any obligations on the Company to retain any Participant as a director nor shall it impose on the part of any Participant any obligation to remain as a director of the Company.

13.4 Withholding of Taxes. The Company shall have the right to deduct from any payment to be made pursuant to the Plan, or to otherwise require, prior to the issuance or delivery of any shares of Common Stock or the payment of any cash thereunder, payment by the Participant of, any Federal, state, local or other taxes required by law to be withheld. Upon the vesting of Restricted Stock (or other Award that is taxable upon vesting), or upon making an election under Section 83(b) of the Code, a Participant shall pay all required withholding to the Company. Any required or permitted withholding obligation with regard to any Participant may be satisfied, subject to the consent of the Committee, by reducing the number of shares of Common Stock otherwise deliverable or by delivering shares of Common Stock already owned, but in any case not in excess of the amount determined based on the maximum statutory tax rate in the applicable jurisdiction. Any fraction of a share of Common Stock required to satisfy such tax obligations shall be disregarded and the amount due shall be paid instead in cash by the Participant.

13.5 Listing and Other Conditions.

(a) Unless otherwise determined by the Committee, as long as the Common Stock is listed on a national securities exchange or system sponsored by a national securities association, the issue of any shares of Common Stock pursuant to an Award shall be conditioned upon such shares being listed on such exchange or system. The Company shall have no obligation to issue such shares unless and until such shares are so listed, and the right to exercise any Stock Option with respect to such shares shall be suspended until such listing has been effected.

(b) If at any time counsel to the Company shall be of the opinion that any sale or delivery of shares of Common Stock pursuant to an Award is or may in the circumstances be unlawful or result in the imposition of excise taxes on the Company under the statutes, rules or regulations of any applicable jurisdiction, the Company shall have no obligation to make such sale or delivery, or to make any application or to effect or to maintain any qualification or registration under the Securities Act or otherwise with respect to shares of Common Stock or Awards, and the right to exercise any Stock Option shall be suspended until, in the opinion of said counsel, such sale or delivery shall be lawful or will not result in the imposition of excise taxes on the Company.

(c) Upon termination of any period of suspension under this Section 13.5any Award affected by such suspension which shall not then have expired or terminated shall be reinstated as to all shares available before such suspension and as to shares which would otherwise have become available during the period of such suspension, but no such suspension shall extend the term of any Stock Option.

(d) A Participant shall be required to supply the Company with any certificates, representations and information that the Company requests and otherwise cooperate with the Company in obtaining any listing, registration, qualification, exemption, consent or approval the Company deems necessary or appropriate.

(e) The Company shall not be obligated to issue any shares of Common Stock to a Participant if, in the opinion of counsel for the Company, the issuance of such Common Stock will constitute a violation by the Participant or the Company of any provisions of any rule or regulation of any governmental authority or any national securities exchange.

13.6 Governing Law. The Plan and actions taken in connection herewith shall be governed and construed in accordance with the laws of the State of Delaware (i.e., the state in which the Company is incorporated, regardless of the law that might otherwise govern under the applicable state law principles governing conflict of laws).

13.7 Construction. Wherever any words are used in the Plan in the masculine gender they shall be construed as though they were also used in the feminine gender in all

cases where they would so apply, and wherever any words are used herein in the singular form they shall be construed as though they were also used in the plural form in all cases where they would so apply.

13.8 Other Benefits. No Award granted or paid under the Plan shall be deemed compensation for purposes of computing benefits under any retirement plan of the Company or its subsidiaries nor affect any benefits under any other benefit plan now or subsequently in effect under which the availability or amount of benefits is related to the level of compensation, except to the extent expressly set forth in any such retirement or other benefit plan.

13.9 Costs. The Company shall bear all expenses included in administering the Plan, including expenses of issuing Common Stock pursuant to any Awards hereunder.

13.10 No Right to Same Benefits. The provisions of Awards need not be the same with respect to each Participant, and such Awards to individual Participants need not be the same in subsequent years.

13.11 Death/Disability. The Committee may in its discretion require the transferee of a Participant to supply it with written notice of the Participant's death or Disability and to supply it with a copy of the will (in the case of the Participant's death) or such other evidence as the Committee deems necessary to establish the validity of the transfer of an Award. The Committee may also require that the agreement of the transferee to be bound by all of the terms and conditions of the Plan.

13.12 Section 16(b) of the Exchange Act. All elections and transactions under the Plan by persons subject to Section 16 of the Exchange Act involving shares of Common Stock are intended to comply with all exemptive conditions under Rule 16b-3. The Committee may establish and adopt written administrative guidelines, designed to facilitate compliance with Section 16(b) of the Exchange Act, as it may deem necessary or proper for the administration and operation of the Plan and the transaction of business thereunder.

13.13 Section 409A of the Code.

(a) Although the Company does not guarantee the particular tax treatment of an Award granted under the Plan, Awards made under the Plan are intended to comply with, or be exempt from, the applicable requirements of Section 409A of the Code and the Plan and any Award agreement hereunder shall be limited, construed and interpreted in accordance with such intent. In no event whatsoever shall the Company or any of its Affiliates be liable for any additional tax, interest or penalties that may be imposed on a Participant by Section 409A of the Code or any damages for failing to comply with Section 409A of the Code.

(b) Notwithstanding anything in the Plan or in an Award to the contrary, the following provisions shall apply to any Award granted under the Plan that constitutes a 409A Covered Award:

(i) A termination of employment shall not be deemed to have occurred for purposes of any provision of a 409A Covered Award providing for payment upon or following a termination of the Participant's employment unless such termination is also a "Separation from Service" within the meaning of Code Section 409A and, for purposes of any such provision of the 409A Covered Award, references to a "termination," "termination of employment" or like terms shall mean Separation from Service. Notwithstanding any provision to the contrary in the Plan or the Award, if the Participant is deemed on the date of the Participant's Termination to be a "specified employee" within the meaning of that term under Section 409A(a)(2)(B) of the Code and using the identification methodology selected by the Company from time to time, or if none, the default methodology set forth in Code Section 409A, then with regard to any such payment under a 409A Covered Award, to the extent required to be delayed in compliance with Section 409A(a)(2)(B) of the Code, such payment shall not be made prior to the earlier of (i) the expiration of the six (6)-month period measured from the date of the Participant's Separation from Service, and (ii) the date of the Participant's death. All payments delayed pursuant to this Section 13.13(b)(i) shall be paid to the Participant on the first day of the seventh month following the date of the Participant's Separation from Service or, if earlier, on the date of the Participant's death.

(ii) Whenever a payment under a 409A Covered Award specifies a payment period with reference to a number of days, the actual date of payment within the specified period shall be within the sole discretion of the Company.

13.14 Successor and Assigns. The Plan shall be binding on all successors and permitted assigns of a Participant, including, without limitation, the estate of such Participant and the executor, administrator or trustee of such estate.

13.15 Severability of Provisions. If any provision of the Plan shall be held invalid or unenforceable, such invalidity or unenforceability shall not affect any other provisions hereof, and the Plan shall be construed and enforced as if such provisions had not been included.

13.16 Payments to Minors, Etc. Any benefit payable to or for the benefit of a minor, an incompetent person or other person incapable of receipt thereof shall be deemed paid when paid to such person's guardian or to the party providing or reasonably appearing to provide for the care of such person, and such payment shall fully discharge the Committee, the Board, the Company, its Affiliates and their employees, agents and representatives with respect thereto.

13.17 Headings and Captions. The headings and captions herein are provided for reference and convenience only, shall not be considered part of the Plan, and shall not be employed in the construction of the Plan

13.18 Recoupment. All Awards granted or other compensation paid by the Company under the Plan, including any shares of Common Stock issued under any Award thereunder, will be subject to: (a) any compensation recapture policies adopted or established by the Board or a committee of the Board from time to time, as it deems advisable, to the extent permitted by applicable law and applicable stock exchange rules, and (b) any compensation recapture policies to the extent required pursuant to any applicable law (including, without limitation, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or other applicable law) or the rules and regulations of any national securities exchange on which the shares of Common Stock are then traded. The Committee shall be permitted, in its sole discretion, to determine at the time an Award is granted to a Participant under the Plan that such Award will be subject to forfeiture and recoupment in the event the Participant violates or breaches any restrictive covenants set forth in a written agreement between the Participant and the Company or any of its Affiliates, including an Award agreement under the Plan.

ARTICLE XIV

EFFECTIVE DATE OF PLAN

The Ensysce Biosciences, Inc. 2021 Omnibus Incentive Plan was originally adopted by the Board on May 26, 2021, and by the stockholders of the Company on June 28, 2021 (the "Original Effective Date"). This amendment and restatement of the Ensysce Biosciences, Inc. 2021 Omnibus Incentive Plan (otherwise referred to herein as the "Plan") was adopted by the Board on November 16, 2021, subject to and effective upon the date the Plan is approved by the stockholders of the Company. The Plan was approved by the stockholders of the Company on January 26, 2022 (the "Restatement Effective Date").

ARTICLE XV

TERM OF PLAN

No Award shall be granted pursuant to the Plan on or after the tenth anniversary of the date the amendment and restatement of the Plan was adopted by the Board (i.e. November 16, 2031), provided that Awards granted prior to such tenth anniversary may extend beyond that date in accordance with the terms and conditions of the Plan.

EXHIBIT A

PERFORMANCE GOALS

Performance Goals established for purposes of the grant and/or vesting of Awards may be based on one or more of the following ("Performance Goals"): (i) the attainment of certain target levels of, or a specified percentage increase in, revenues, earnings, income before taxes and non-recurring items, net income, operating income, earnings before income tax, earnings before interest, taxes, depreciation and amortization or a combination of any or all of the foregoing; (ii) the attainment of certain target levels of, or a percentage increase in, after-tax or pre-tax profits including, without limitation, that attributable to continuing and/or other operations; (iii) the attainment of certain target levels of, or a specified increase in, operational cash flow; (iv) the achievement of a certain level of, reduction of, or other specified objectives with regard to limiting the level of increase in, all or a portion of, the Company's bank debt or other long-term or short-term public or private debt or other similar financial obligations of the Company, which may be calculated net of such cash balances and/or other offsets and adjustments as may be established by the Committee; (v) earnings per share or the attainment of a specified percentage increase in earnings per share or earnings per share from continuing operations; (vi) the attainment of certain target levels of, or a specified increase in return on, capital employed or return on invested capital; (vii) the attainment of certain target levels of, or a percentage increase in, after-tax or pre-tax return on stockholders' equity; (viii) the attainment of certain target levels of, or a specified increase in, economic value added targets based on a cash flow return on investment formula; (ix) the attainment of certain target levels in, or specified increases in, the fair market value of the shares of the Company's common stock; (x) the growth in the value of an investment in the Company's common stock assuming the reinvestment of dividends; (xi) the filing of a new drug application ("NDA") or the approval of the NDA by the Food and Drug Administration; (xii) the achievement of a launch of a new drug; (xiii) research and development milestones; (xiv) the successful completion of clinical trial phases, (xv) the attainment of a certain level of, reduction of, or other specified objectives with regard to limiting the level in or increase in, all or a portion of controllable expenses or costs or other expenses or costs; (xvi) gross or net sales, revenue and growth of sales revenue (either before or after cost of goods, selling and general administrative expenses, research and development expenses and any other expenses or interest); (xvii) total stockholder return; (xviii) return on assets or net assets; (xix) return on sales; (xx) operating profit or net operating profit; (xxi) operating margin; (xxii) gross or net profit margin; (xxiii) cost reductions or savings or other expense control targets; (xxiv) productivity or productivity ratios; (xxv) operating efficiency; (xxvi) customer satisfaction; (xxvii) working capital; (xxviii) market share; (xxix) strategic business criteria, consisting of one or more objectives based on meeting specified revenue, market penetration, geographic business expansion goals, objectively identified project milestones, production volume levels, cost targets, and goals relating to acquisitions or divestitures; (xxx) aggregate product price and other product price measures; (xxxi) safety record; (xxxii) personal management objectives or achievement of objective business and operational goals, such as market share, new products, and/or business development; and (xxxiii) achievement of specified milestones in the manufacturing or commercialization of one or more of our products.

The foregoing list of Performance Goals is not exhaustive and the Committee shall have the discretion to establish such other Performance Goals as the Committee deems appropriate from time to time. In addition, such Performance Goals may be based upon the attainment of specified levels of Company (or subsidiary, division, other operational unit or administrative department of the company) performance under one or more of the Performance Goals either in absolute terms or as compared to any incremental increase or decrease or as compared to results of a peer group or to market performance indicators or indices.

The Committee may, in its sole discretion, provide that one or more adjustments shall be made to one or more of the Performance Goals. Such adjustments may include, without limitation, one or more of the following: (i) items related to a change in accounting principle; (ii) items relating to financing activities; (iii) expenses for restructuring or productivity initiatives; (iv) other non-operating items; (v) items related to acquisitions; (vi) items attributable to the business operations of any entity acquired by the Company during the period over which the Performance Goals are measured; (vii) items related to the disposal of a business or segment of a business; items related to discontinued operations that do not qualify as a segment of a business under Generally Accepted Accounting Principles ("GAAP"); (viii) items attributable to any stock dividend, stock split, combination or exchange of stock occurring during the period over which the Performance Goals are measured; (ix) any other items of significant income or expense which are determined to be appropriate adjustments; (x) items relating to unusual or extraordinary corporate transactions, events or developments; (xi) items related to amortization of acquired intangible assets; (xii) items that are outside the scope of the Company's core, on-going business activities; (xiii) items related to acquired in-process research and development; (xiv) items relating to changes in tax laws; (xv) items relating to major licensing or partnership arrangements; (xvi) items relating to asset impairment charges; (xvii) items relating to gains or losses for litigation, arbitration and contractual settlements; (xviii) items attributable to expenses incurred in connection with a reduction in force or early retirement initiative; (xix) items relating to any other unusual or nonrecurring events or changes in applicable law, accounting principles or business conditions; or (xx) such other adjustments the Committee determines appropriate, in its sole discretion, taking into account such factors that the Committee deems relevant. The Committee shall have the discretion to determine whether, when and to what extent an adjustment is necessary or advisable based upon consideration of such factors the Committee deems appropriate in light of the facts and circumstances.

ENSYSCE BIOSCIENCES, INC. AMENDED AND RESTATED 2021 OMNIBUS INCENTIVE PLAN

STOCK OPTION GRANT NOTICE AND AWARD AGREEMENT

Ensysce Biosciences, Inc., a Delaware corporation (the "Company"), pursuant to its 2021 Amended and Restated Omnibus Incentive Plan (the "Plan"), hereby grants to the individual listed below ("Participant") an option to purchase the number of shares of Common Stock (the "Shares") set forth below (the "Option"). The Option described in this Stock Option Grant Notice (the "Grant Notice") is subject to the terms and conditions set forth in the Award Agreement attached hereto as Exhibit A (the "Agreement") and the Plan, each of which is incorporated herein by reference. Unless otherwise defined herein, capitalized terms used in this Grant Notice and the Agreement will have the meanings defined in the Plan.

Participant:	[_____]
Grant Date:	[_____]
Exercise Price Per Share:	[_____]
Total Number of Shares Subject to Option:	[_____]
Expiration Date:	[_____]
Type of Option:	☐ Incentive Stock Option (to the extent permitted by 422(d) of the Code) ☐ Non-Qualified Stock Option
Vesting Schedule:	[_____]

By signing below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and this Grant Notice. This document may be executed, including by electronic means, in multiple counterparts, each of which will be deemed an original, and all of which together will be deemed a single instrument.

ENSYSCE BIOSCIENCES, INC.	**PARTICIPANT**
Name: Title:	Name:

EXHIBIT A
TO STOCK OPTION GRANT NOTICE

AWARD AGREEMENT

1. Award of Option. Effective as of the Grant Date set forth in the Grant Notice, the Company has granted to Participant the Option to purchase part or all of the aggregate number of Shares set forth in the Grant Notice, subject to the terms and conditions set forth in the Grant Notice, the Plan and this Agreement.

2. Term of Option. The Option may not be exercised later than the Expiration Date set forth in the Grant Notice, subject to earlier termination in accordance with the Plan and this Agreement.

3. Option Exercise Price. The exercise price per Share of the Option (the "Exercise Price") is set forth in the Grant Notice.

4. Vesting and Exercise of Option. Subject to the continued service of Participant with the Company through the relevant vesting dates, the Option shall become vested and exercisable in such amounts and at such times as set forth in the Grant Notice. In addition:

a. Accelerated Vesting upon Death. Upon Participant's Termination by reason of death, any portion of the Option that is outstanding and unvested immediately prior to Participant's death will fully vest and become exercisable on the date of Participant's death, provided that Participant's estate and beneficiaries execute a general release of claims against the Company and its affiliates in a form reasonably prescribed by the Company and such releases become irrevocable within forty-five (45) days following Participant's death. If the release requirement described above is not timely satisfied, any portion of the Option otherwise vesting under this Section 4.a will be forfeited. To the extent vested, the Option will be exercisable for the period of time set forth in Section 6.4(a) of the Plan.

b. Effect of Termination of Service on the Option. Unless otherwise provided in the Grant Notice, this Agreement or any written employment agreement between Participant and the Company that expressly addresses treatment of stock option grants under the Plan, the termination or survival of the Option upon the Termination of Participant will be determined in accordance with Section 6.4 of the Plan.

c. Service with Affiliates. Solely for purposes of this Agreement, service with the Company will be deemed to include service with an Affiliate of the Company (for only so long as such entity remains an Affiliate of the Company).

d. Method of Exercise. Participant may exercise the Option only to the extent it is vested. To exercise the Option, Participant must give written notice of exercise to the Company specifying the number of shares of Common Stock to be purchased, accompanied by payment in full of the aggregate Exercise Price in accordance with Section 6.3(d) of the Plan. Such notice must specify the date (not to exceed more than ninety (90) days after the date of such notice) on which the shares will be purchased and be accompanied by any further documents or instruments the Company deems necessary or desirable to carry out the purposes or intent of this Agreement.

e. Partial Exercise. The Option may be exercised in whole or in part, provided, however, that the minimum number of Shares with respect to which the Option may be exercised is one hundred (100). If less than one hundred (100) Shares remain outstanding under the Option at any time, the Option may only be exercised in whole. Any exercise may apply only with a whole number of Shares.

f. Conditions of Exercise. The Option may not be exercised, and any purported exercise will be void, if the issuance of Shares upon such exercise would constitute a violation of any law, regulation, or exchange listing requirement. The Committee may from time to time modify the terms of the Option or impose additional conditions on the exercise of the Option as it deems necessary or appropriate to facilitate compliance with any law, regulation or exchange listing requirement.

g. Rights as Stockholder. The Option will not confer upon Participant any of the rights or privileges of a stockholder in the Company unless and until

Participant is issued Shares following Participant's exercise of the Option.

5. Non-Transferability of Option. Participant may not anticipate, alienate, attach, sell, assign, pledge, encumber, charge or otherwise transfer the Option other than by will or by the laws of descent and distribution. The Option shall be exercisable, during Participant's lifetime, only by Participant.

6. Adjustments. The Exercise Price, as well as the number and kind of shares subject to the Option, are subject to adjustment in accordance with Section 4.2 of the Plan.

7. No Continuation of Service. Neither the Plan nor this Agreement will confer upon Participant any right to continue in the employment or service of the Company or any of its Affiliates, or limit in any respect the right of the Company or its Affiliates to discharge Participant at any time, for any reason.

8. Withholding.

a. Regardless of any action the Company takes with respect to any or all income tax, payroll tax or other tax-related withholding ("Tax-Related Items"), Participant acknowledges that the ultimate liability for all Tax-Related Items owed by Participant is and remains Participant's responsibility and that the Company (i) makes no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Option, including the grant, vesting or exercise of the Option or the subsequent sale of Shares acquired upon exercise; and (ii) does not commit to structure the terms of the grant or any aspect of the Option to reduce or eliminate Participant's liability for Tax-Related Items.

b. Prior to exercise of the Option, Participant shall pay or make adequate arrangements satisfactory to the Company to satisfy all withholding obligations of the Company. In this regard, Participant authorizes the Company to withhold all applicable Tax-Related Items legally payable by Participant from Participant's wages or other cash compensation paid to Participant by the Company or from proceeds of the sale of the Shares. Alternatively, or in addition, to the extent permissible under applicable law, the Company may (i) sell or arrange for the sale of Shares that Participant acquires to meet the withholding obligation for Tax-Related Items, and/or (ii) withhold Shares otherwise issuable upon exercise of the Option, provided that the Company only withholds the amount of Shares necessary to satisfy the withholding amount (not to exceed maximum statutory rates). Finally, Participant shall pay to the Company any amount of Tax-Related Items that the Company may be required to withhold as a result of Participant's participation in the Plan that cannot be satisfied by the means previously described. The Company may refuse to issue and deliver Shares upon exercise of the Option if Participant fails to comply with Participant's obligations in connection with the Tax-Related Items as described in this Section 8.

9. The Plan. A prospectus describing the Plan has been furnished to Participant. The Plan itself is available upon request, and its terms and provisions are incorporated herein by reference. sPursuant to the Plan, the Committee is authorized to construe and interpret the terms and provisions of the Plan and to adopt rules and regulations not inconsistent with the Plan as it deems necessary to carry the Plan into effect. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Committee with respect to questions arising under the Plan, the Grant Notice or this Agreement.

10. Company Policies. Participant agrees, in consideration for the grant of the Option, to be subject to any policies by the Company and its Affiliates regarding compensation recapture (i.e., clawbacks), securities trading, and hedging or pledging of securities that may be in effect from time to time, or as may otherwise be required by applicable law, regulation or exchange listing standard.

11. Entire Agreement. The Grant Notice and this Agreement, together with the Plan, represent the entire agreement between the parties with respect to the subject matter hereof and supersede any prior agreement, written or otherwise, relating to the subject matter hereof.

12. Amendment. This Agreement may only be amended by a writing signed by each of the parties hereto; provided that the Company may amend this Agreement without Participant's consent, if the amendment does not impair Participant's rights hereunder or as otherwise permitted in Section 4.f above.

13. Governing Law. This Agreement will be construed in accordance with the laws and judicial decisions of the State of Delaware, without regard to the application of the principles of conflicts of laws.

14. Headings. The headings in this Agreement are for convenience only. They form no part of the Agreement and will not affect its interpretation.

15. Incentive Stock Options.

a. If the Option is designated as an Incentive Stock Option, Participant acknowledges that nonetheless a portion of the Option may not qualify (or may cease to qualify) as an "incentive stock option" under the Code due to limitations set forth in Section 422(d) of the Code or otherwise. To the extent the Option does not qualify for treatment as an "incentive stock option" under the Code, it will be treated as a Non-Qualified Stock Option. The Company does not guarantee any particular tax treatment for the Option or the Shares subject to the Option.

b. If the Option is designed as an Incentive Stock Option, Participant shall give prompt written notice to the Company of any disposition or other transfer of any Shares acquired under the Option, if such disposition or transfer is made (i) within two years from the Grant Date, or (ii) within one year after the transfer of such Shares to Participant. Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by Participant in such disposition or other transfer.

16. Electronic Delivery of Documents. Participant authorizes the Company to deliver electronically any prospectuses or other documentation related to the Option and any other compensation or benefit plan or arrangement in effect from time to time (including, without limitation, reports, proxy statements or other documents that are required to be delivered to participants in such arrangements pursuant to federal or state laws, rules or regulations). For this purpose, electronic delivery will include, without limitation, delivery by means of e-mail or e-mail notification that such documentation is available on the Company's Intranet site. Upon written request, the Company will provide to Participant a paper copy of any document also delivered to Participant electronically. The authorization described in this paragraph may be revoked by Participant at any time by written notice to the Company.

17. Further Assurances. Participant agrees, upon demand of the Company or the Committee, to do all acts and execute, deliver and perform all additional documents, instruments and agreements which may be reasonably required by the Company or the Committee, as the case may be, to implement the provisions and purposes of this Agreement and the Plan.

18. Restrictive Covenants. To the extent allowed by and consistent with applicable law and any applicable limitations period, if it is determined at any time that Participant has materially breached any employment-related covenants, the Company will be entitled to cause any unvested portion of the Option to be immediately cancelled without any payment of consideration by the Company.

Exhibit 10.30c

SETTLEMENT AGREEMENT AND MUTUAL GENERAL RELEASE

This **SETTLEMENT AGREEMENT AND MUTUAL GENERAL RELEASE** ("**Agreement**"), is made and entered into effective this August 3, 2021 (the "**Effective Date**"), by and among DelMorgan Group LLC ("**DelMorgan**") Globalist Capital, LLC ("**Globalist**" and, together with DelMorgan, "**Advisor**") and D. Lynn Kirkpatrick, Ph.D. ("**Kirkpatrick")** and Ensysce Biosciences, Inc. (the "**Company**"). Collectively, Advisor, Company, and Kirkpatrick are referred to herein individually as a "**Party**" or collectively, as "**Parties**." Capitalized terms used and not otherwise defined herein shall have the meanings given to such terms in the Email Agreement (defined below).

WHEREAS, on January 31, 2021, the Company entered into an Agreement and Plan of Merger (the "**Merger Agreement**") by and among Leisure Acquisition Corp. ("**LACQ**"), EB Merger Sub, Inc., a wholly owned subsidiary of LACQ ("**Merger Sub**"), providing for, among other things, and subject to the terms and conditions therein, the business combination between LACQ and the Company pursuant to the merger of Merger Sub with and into the Company, with the Company continuing as the surviving entity (the "**Merger**");

WHEREAS, on January 26, 2021, Company and Advisor amended their previous letter agreement dated as of March 6, 2020 ("**Letter Agreement**") and with an email agreement dated as of January 31, 2021 (the "**Email Agreement**");

WHEREAS, pursuant to the Email Agreement the Advisor agreed to accept 500,000 private placement warrants (as such term is defined in the prospectus for LACQ's initial public offering) ("**Advisor Warrants**") and 500,000 shares of LACQ's Common Stock, now Ensysce Common Stock (the "**Advisor Shares**"), none of which shall be subject to any lock-up, immediately after the closing of the Merger as its sole and complete compensation and consideration under the Agreement, including without limitation with respect to the Share Purchase Agreement dated as of December 29, 2020 by and among Ensysce, GEM Global Yield LLC SCS and GEM Yield Bahamas Limited;

WHEREAS, the parties entered into Amendment No. 1 the Email Agreement (the "**Amendment**") to provide that instead of the 500,000 private placement warrants Advisor was to receive at the close of the Merger, Advisor received 500,000 replacement warrants which included restrictions on transferability;

WHEREAS, a dispute has now arisen concerning the nature of the promises made by the Company and Kirkpatrick with respect to the Email Agreement and the Amendment, which has resulting in the filing of the lawsuit styled as *DelMorgan Group, LLC et al. v. Ensysce Biosciences, Inc., et al.,* Los Angeles County Superior Court, Case Number 21 STCV25585 (the "**Lawsuit**");

WHEREAS, without admitting fault, the parties desire to enter into this Agreement to settle the Lawsuit, and in furtherance thereof to, among other matters, provide for (a) the registration of the Advisor's Shares and the shares underlying the Advisor Warrants and (b) to provide for cashless exercise of the Advisor Warrants, and, in exchange therefor, (c) Advisor agrees to withdraw and dismiss with prejudice the Lawsuit, as defined below;

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. **Registration of Shares of Common Stock**. Ensysce shall include the Advisor Shares and the shares of Common Stock underlying the Advisor Warrants on its Registration Statement on Form S-1 ("**S-1**") to be filed with the Securities and Exchange Commission as soon as possible and in all events within ten days of the Effective Date. Ensysce shall use best efforts to have the S-1 declared effective as soon as possible following its filing and shall notify Advisor of the effectiveness of the S-1 at such time. For the avoidance of doubt, the Advisor Warrants shall not be registered in the S-1, but the Common Stock underlying the Advisor Warrants shall be registered in the S-1.

2. **Confirmation of Terms of Advisors Warrants.** The Advisors Warrants shall be amended and restated to reflect an Exercise Price of $10.00. The Advisor Warrants shall be deemed to have a "cashless exercise" feature, permitting the Advisor to exercise using the cashless exercise feature found in the form Warrant Agreement filed with the SEC (Exhibit 4.1) in Section 3.3.1(c) and which is set forth on Appendix A thereof.

3. **Dismissal of Lawsuit with Prejudice.** Advisor agrees that the lawsuit filed in the Superior Court of Los Angeles County on or about July 14, 2021, Case Number 21 STCV25585, filed by Del Morgan and Globalist, as Plaintiffs, and Ensysce and D. Lynn Kirkpatrick, as Defendants ("Lawsuit") shall be dismissed with prejudice within five business days of notification that the S-1 has become effective. The dismissal shall request that the Court retain jurisdiction over this matter pursuant to California Code of Civil Procedure § 664.6 Upon full execution of this Agreement, DelMorgan shall file with the Court a Notice of Conditional Settlement, indicating that the conditions to the settlement are likely to be satisfied within 45 days. Except as provided in Section 2 and 3 of this Agreement, the Parties agree to stay any action on the Lawsuit after the S-1 is filed to allow for SEC review/effectiveness of the S-1 which the Company agrees to use best efforts to seek effectiveness as soon as possible.

4. **Mutual General Releases.**

(a) Release of Advisor. In consideration of the promises set forth in this Agreement, Kirkpatrick and Company, and each of them, on behalf of their respective members, partners, representatives, attorneys, executors, administrators, successors, and assigns, hereby releases, acquits, withdraws, and forever discharges Advisor and all of their members, partners, representatives, attorneys, executors, administrators, successors, and assigns, from any and all actions, causes of action, obligations, costs, expenses, damages, losses, claims, liabilities, suits, debts, demands, and benefits (including actual attorneys' fees and costs), of whatever character, in law or equity, known or unknown, suspected or unsuspected, matured or unmatured, of any kind or nature whatsoever, now existing or arising in the future, based on any act, omission, event, occurrence or nonoccurrence from the beginning of time to the date of full execution of this Agreement, arising from or related to the Letter Agreement, the E-Mail Agreement, the Amendment, or the Lawsuit.

(b) Release of Company and Kirkpatrick. In consideration of the promises set forth in this Agreement, Advisor, and each of them, on behalf of their members, partners, representatives, attorneys, executors, administrators, successors, and assigns, hereby releases, acquits, withdraws, and forever discharges Advisor and all of their members, partners, representatives, attorneys, executors, administrators, successors, and assigns, from any and all actions, causes of action, obligations, costs, expenses, damages, losses, claims, liabilities, suits, debts, demands, and benefits (including actual attorneys' fees and costs), of whatever character, in law or equity, known or unknown, suspected or unsuspected, matured or unmatured, of any kind or nature whatsoever, now existing or arising in the future, based on any act, omission, event, occurrence or nonoccurrence from the beginning of time to the date of full execution of this Agreement, arising from or related to the Letter Agreement, the E-Mail Agreement, the Amendment, of the Lawsuit.

5. **Assumption of Risk and Waiver of Unknown Claims.** For the purpose of implementing a full and complete release, the Parties expressly acknowledge that the release they give in this Agreement is intended to include in its effect, without limitation, claims that they did not know or suspect to exist in their favor at the time of the effective date of this Agreement, regardless of whether the knowledge of such claims, or the facts upon which they might be based, would materially have affected the settlement of this matter, and that the consideration given under this Agreement was also for the release of those claims and contemplates the extinguishment of any such unknown claims. In furtherance of the settlement, the Parties waive any rights they may have under California Code of Civil Procedure § 1542 (and other similar statutes and regulations), which states:

"A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY."

6. **Each Party to Bear Own Costs and Fees**. Each Party shall bear their own attorneys' fees and other costs (including costs of expert witnesses or other consultants) incurred in relation to the Purchase Agreement and in the preparation, negotiation, and drafting of this Agreement.

7. **Reaffirmation by Parties**. The E-Mail Agreement, as expressly modified by the Amendment and this Agreement, shall remain in full force and effect. The Letter Agreement, as expressly modified by the E-mail Agreement, the Amendment and this Agreement, shall remain in full force and effect.

8. **Third Party Beneficiaries.** Except as stated herein, there are no third-party beneficiaries to this Agreement.

9. **Comprehension of Agreement.** By signing this Agreement, the Parties acknowledge that they have read it in its entirety and represent and warrant that they understand it in its entirety.

10. **Representation by Counsel.** The Parties hereto represent that they have received or had the opportunity to receive advice from independent counsel of their own choice and have signed this Agreement freely and without duress.

11. **No Construction Against Drafter.** Each of the Parties agree that each has participated in arriving at the final language of this Agreement, and, therefore, this Agreement shall not be construed against any Party as drafter.

12. **Covenant to Take Further Actions Necessary.** The Parties hereby agree to cooperate fully and to execute such other documents and to take such other action as may be reasonably necessary to further the purpose of this Agreement, with the Parties to bear their own costs and attorneys' fees for these additional actions.

13. **Continuing Duty to Cooperate.** The Parties hereto shall, at any time hereafter, make, execute, and deliver any and all papers or documents as any Party hereto may reasonably require for the purpose of giving full effect to this Agreement and each of its provisions.

14. **Integrated Agreement.** Expect as expressly stated herein, this Agreement sets forth the entire Agreement and understanding between the Parties relating to the subject matter herein and supersedes all prior discussions between the Parties.

15. **Waiver, Modification, And Amendment.** No modification or amendment to this Agreement shall be effective unless in writing signed by the Parties' whose rights or obligations are affected by such modification or amendment. Any subsequent change or changes to any Party's duties, obligations, rights, etc. shall not affect the validity or scope of this Agreement.

16. **Severability.** If any provision of this Agreement or part thereof shall be held by a court or other tribunal of competent jurisdiction to be unenforceable, then such provision or part thereof shall be excised here from and the remaining provisions of this Agreement and parts thereof shall remain in full force and effect.

17. **Attorney's Fees, Costs, and Enforcement.** This Agreement shall be binding and enforceable under Code of Civil Procedure Section 664.6. In any litigation, arbitration, or other proceeding in any way arising under or relating to this agreement, including to enforce this contract (regardless of the nature of the claim) or to obtain a declaration of any rights or obligations under this contract, the prevailing party shall be awarded its reasonable attorney fees, and costs and expenses incurred.

18. **Assignment of Claims**. Each of the Parties represents to all other Parties that there has been no assignment or any transfer of any right, title or interest in any claim, action, cause of action, obligation, or liability whatsoever that (i) a Party may have or has had against any other Party hereto or (ii) authorized any other person or entity to assert such on its behalf, or (iii) is being released pursuant to this Agreement.

19. **Authority**. Each individual signing this Agreement warrants and represents that he or she has full authority to execute the same on behalf of the Party on whose behalf he or she so signed, and that he or she is acting in the course and scope of such authority, and is duly authorized to execute this Agreement.

20. **GOVERNING LAW**. THIS AMENDMENT IS GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF CALIFORNIA, WITHOUT REGARD FOR THE PROVISIONS THEREOF REGARDING CHOICE OF LAW THAT WOULD APPLY THE LAW OF A DIFFERENT JURISDICTION.

21. **Multiple Counterparts**. For the convenience of the parties hereto, this Agreement may be signed in multiple counterparts, each of which will be deemed an original, and all counterparts hereof so signed by the parties hereto, whether or not such counterpart will bear the execution of each of the Parties hereto, will be deemed to be, and is to be construed as, one and the same agreement. A facsimile or electronic scan in "PDF" format of a signed counterpart of this Agreement will be sufficient to bind the Party or Parties whose signature(s) appear thereon.

22. **Binding Effect; Assignment.** This Agreement is binding upon, and will inure to the benefit of and are enforceable by, the parties and their respective successors, representatives and permitted assigns. No Party to this Agreement may assign this Agreement, by operation of law or otherwise, in whole or in part, without the prior written consent of the other parties, and any purported assignment made or attempted in violation of this section will be null and void.

[Signatures Page Follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be signed by their duly authorized officers as of the date first above written.

DELMORGAN GROUP LLC

By: */s/ Neil Morganbesser*
Name: Neil Morganbesser
Title: CEO

GLOBALIST CAPITAL, LLC

By: */s/ Neil Morganbesser*
Name: Neil Morganbesser
Title: CEO

ENSYSCE BIOSCIENCES, INC.

By: */s/ Lynn Kirkpatrick*
Lynn Kirkpatrick
Chief Executive Officer

D. LYNN KIRKPATRICK, Ph.D.

/s/D. Lynn Kirkpatrick
D. Lynn Kirkpatrick, Ph.D.

[Signature Page to Settlement Agreement and Mutual General Release]

Appendix A

Cashless Exercise Feature. Upon surrender of the Advisor Warrant it shall receive that number of shares of Common Stock equal to the quotient obtained by dividing (x) the product of the number of shares of Common Stock underlying the Warrants multiplied by the difference between the Warrant Price and the Fair Market Value by (y) the Fair Market Value. The Warrant Price shall mean $10.00 per share. The Fair Market Value shall mean the average reported last sale price of the Common Stock for the ten trading days ending on the third trading day prior to the date on which notice of the exercise of the Warrant is sent to the Warrant Agent.

By way of example, if Warrants for 500,000 shares are tendered, the Warrant Price is $10.00 and the Fair Market Value is $20.00, then:

500,000 x (20.00 - 10.00)/20.00 = 250,000 shares of Common Stock would be issued in full satisfaction of the Advisor Warrant. The Common Stock underlying the Advisor Warrants having been registered with the SEC are freely tradeable and without any further restriction on transfer.

[Signature Page to Settlement Agreement and Mutual General Release]

ENSYSCE BIOSCIENCES, INC.

AMENDED AND RESTATED 2021 OMNIBUS INCENTIVE PLAN

STOCK OPTION GRANT NOTICE AND AWARD AGREEMENT

Ensysce Biosciences, Inc., a Delaware corporation (the "Company"), pursuant to its 2021 Amended and Restated Omnibus Incentive Plan (the "Plan"), hereby grants to the individual listed below ("Participant") an option to purchase the number of shares of Common Stock (the "Shares") set forth below (the "Option"). The Option described in this Stock Option Grant Notice (the "Grant Notice") is subject to the terms and conditions set forth in the Award Agreement attached hereto as Exhibit A (the "Agreement") and the Plan, each of which is incorporated herein by reference. Unless otherwise defined herein, capitalized terms used in this Grant Notice and the Agreement will have the meanings defined in the Plan.

Participant:	David J. Kovacs
Grant Date:	February 14, 2022
Exercise Price Per Share:	$6.28
Total Number of Shares Subject to Option:	500,000
Expiration Date:	February 14, 2032
Type of Option:	☐ Incentive Stock Option (to the extent permitted by 422(d) of the Code) ☒ Non-Qualified Stock Option
Vesting Schedule:	Immediately vested
Termination:	This Option does not terminate and need not be exercised upon Participant ceasing to be engaged as a consultant to the Company but shall remain exercisable through the Expiration Date.

[Signature Page to Follow]

By signing below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and this Grant Notice. This document may be executed, including by electronic means, in multiple counterparts, each of which will be deemed an original, and all of which together will be deemed a single instrument.

ENSYSCE BIOSCIENCES, INC.	**PARTICIPANT**
/s/ David Humphrey	*/s/ David J. Kovacs*
Name: David Humphrey Title: Chief Financial Officer	Name: David J. Kovacs

EXHIBIT A
TO STOCK OPTION GRANT NOTICE

AWARD AGREEMENT

1. Award of Option. Effective as of the Grant Date set forth in the Grant Notice, the Company has granted to Participant the Option to purchase part or all of the aggregate number of Shares set forth in the Grant Notice, subject to the terms and conditions set forth in the Grant Notice, the Plan and this Agreement.

2. Term of Option. The Option may not be exercised later than the Expiration Date set forth in the Grant Notice, subject to earlier termination in accordance with the Plan and this Agreement.

3. Option Exercise Price. The exercise price per Share of the Option (the "Exercise Price") is set forth in the Grant Notice.

4. Vesting and Exercise of Option. Subject to the continued service of Participant with the Company through the relevant vesting dates, the Option shall become vested and exercisable in such amounts and at such times as set forth in the Grant Notice. In addition:

a. Effect of Termination of Service on the Option. Unless otherwise provided in the Grant Notice, this Agreement or any written employment agreement between Participant and the Company that expressly addresses treatment of stock option grants under the Plan, the termination or survival of the Option upon the Termination of Participant will be determined in accordance with Section 6.4 of the Plan.

b. Service with Affiliates. Solely for purposes of this Agreement, service with the Company will be deemed to include service with an Affiliate of the Company (for only so long as such entity remains an Affiliate of the Company).

c. Method of Exercise. Participant may exercise the Option only to the extent it is vested. To exercise the Option, Participant must give written notice of exercise to the Company specifying the number of shares of Common Stock to be purchased, accompanied by payment in full of the aggregate Exercise Price in accordance with Section 6.3(d) of the Plan. Such notice must specify the date (not to exceed more than ninety (90) days after the date of such notice) on which the shares will be purchased and be accompanied by any further documents or instruments the Company deems necessary or desirable to carry out the purposes or intent of this Agreement.

d. Partial Exercise. The Option may be exercised in whole or in part, provided, however, that the minimum number of Shares with respect to which the Option may be exercised is one hundred (100). If less than one hundred (100) Shares remain outstanding under the Option at any time, the Option may only be exercised in whole. Any

exercise may apply only with a whole number of Shares.

e. Conditions of Exercise. The Option may not be exercised, and any purported exercise will be void, if the issuance of Shares upon such exercise would constitute a violation of any law, regulation, or exchange listing requirement. The Committee may from time to time modify the terms of the Option or impose additional conditions on the exercise of the Option as it deems necessary or appropriate to facilitate compliance with any law, regulation or exchange listing requirement.

f. Rights as Stockholder. The Option will not confer upon Participant any of the rights or privileges of a stockholder in the Company unless and until Participant is issued Shares following Participant's exercise of the Option.

5. Non-Transferability of Option. Participant may not anticipate, alienate, attach, sell, assign, pledge, encumber, charge or otherwise transfer the Option other than by will or by the laws of descent and distribution. The Option shall be exercisable, during Participant's lifetime, only by Participant.

6. Adjustments. The Exercise Price, as well as the number and kind of shares subject to the Option, are subject to adjustment in accordance with Section 4.2 of the Plan.

7. No Continuation of Service. Neither the Plan nor this Agreement will confer upon Participant any right to continue in the employment or service of the Company or any of its Affiliates, or limit in any respect the right of the Company or its Affiliates to discharge Participant at any time, for any reason.

8. Withholding.

a. Regardless of any action the Company takes with respect to any or all income tax, payroll tax or other tax-related withholding ("Tax-Related Items"), Participant acknowledges that the ultimate liability for all Tax-Related Items owed by Participant is and remains Participant's responsibility and that the Company (i) makes no representations or undertakings regarding the treatment of any Tax- Related Items in connection with any aspect of the Option, including the grant, vesting or exercise of the Option or the subsequent sale of Shares acquired upon exercise; and (ii) does not commit to structure the terms of the grant or any aspect of the Option to reduce or eliminate Participant's liability for Tax-Related Items.

b. Prior to exercise of the Option, Participant shall pay or make adequate arrangements satisfactory to the Company to satisfy all withholding obligations of the Company. In this regard, Participant authorizes the Company to withhold all applicable Tax-Related Items legally payable by Participant from Participant's wages or other cash compensation paid to Participant by the Company or from proceeds of the sale of the Shares. Alternatively, or in addition, to the extent permissible under applicable law, the Company may (i) sell or arrange for the sale of Shares that Participant acquires to meet the withholding obligation for Tax-Related Items, and/or (ii) withhold Shares otherwise issuable upon exercise of the Option, provided that the Company only withholds the amount of Shares necessary to satisfy the withholding amount (not to exceed maximum statutory rates). Finally, Participant shall pay to the Company any amount of Tax-Related Items that the Company may be required to withhold as a result of Participant's participation in the Plan that cannot be satisfied by the means previously described. The Company may refuse to issue and deliver Shares upon exercise of the Option if Participant fails to comply with Participant's obligations in connection with the Tax-Related Items as described in this Section 8.

9. The Plan. A prospectus describing the Plan has been furnished to Participant. The Plan itself is available upon request, and its terms and provisions are incorporated herein by reference. Pursuant to the Plan, the Committee is authorized to construe and interpret the terms and provisions of the Plan and to adopt rules and regulations not inconsistent with the Plan as it deems necessary to carry the Plan into effect. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Committee with respect to questions arising under the Plan, the Grant Notice or this Agreement.

10. Company Policies. Participant agrees, in consideration for the grant of the Option, to be subject to any policies by the Company and its Affiliates regarding compensation recapture (i.e., clawbacks), securities trading, and hedging or pledging of securities that may be in effect from time to time, or as may otherwise be required by applicable law, regulation or exchange listing standard.

11. Entire Agreement. The Grant Notice and this Agreement, together with the Plan, represent the entire agreement between the parties with respect to the subject matter hereof and supersede any prior agreement, written or otherwise, relating to the subject matter hereof.

12. Amendment. This Agreement may only be amended by a writing signed by each of the parties hereto; provided that the Company may amend this Agreement without Participant's consent, if the amendment does not impair Participant's rights hereunder or as otherwise permitted in Section 4.e above.

13. Governing Law. This Agreement will be construed in accordance with the laws and judicial decisions of the State of Delaware, without regard to the application of the principles of conflicts of laws.

14. Headings. The headings in this Agreement are for convenience only. They form no part of the Agreement and will not affect its interpretation.

15. Incentive Stock Options.

a. If the Option is designated as an Incentive Stock Option, Participant acknowledges that nonetheless a portion of the Option may not qualify (or may cease to qualify) as an "incentive stock option" under the Code due to limitations set forth in Section 422(d) of the Code or otherwise. To the extent the Option does not qualify for treatment as an "incentive stock option" under the Code, it will be treated as a Non-Qualified Stock Option. The Company does not guarantee any particular tax treatment for the Option or the Shares subject to the Option.

b. If the Option is designed as an Incentive Stock Option, Participant shall give prompt written notice to the Company of any disposition or other transfer of any Shares acquired under the Option, if such disposition or transfer is made (i) within two years from the Grant Date, or (ii) within one year after the transfer of such Shares to Participant. Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by Participant in such disposition or other transfer.

16. Electronic Delivery of Documents. Participant authorizes the Company to deliver electronically any prospectuses or other documentation related to the Option and any other compensation or benefit plan or arrangement in effect from time to time (including, without limitation, reports, proxy statements or other documents that are required to be delivered to participants in such arrangements pursuant to federal or state laws, rules or regulations). For this purpose, electronic delivery will include, without limitation, delivery by means of e-mail or e-mail notification that such documentation is available on the Company's Intranet site. Upon written request, the Company will provide to Participant a paper copy of any document also delivered to Participant electronically. The authorization described in this paragraph may be revoked by Participant at any time by written notice to the Company.

17. Further Assurances. Participant agrees, upon demand of the Company or the Committee, to do all acts and execute, deliver and perform all additional documents, instruments and agreements which may be reasonably required by the Company or the Committee, as the case may be, to implement the provisions and purposes of this Agreement and the Plan.

18. Restrictive Covenants. To the extent allowed by and consistent with applicable law and any applicable limitations period, if it is determined at any time that Participant has materially breached any employment-related covenants, the Company will be entitled to cause any unvested portion of the Option to be immediately cancelled without any payment of consideration by the Company.

ENSYSCE BIOSCIENCES, INC.

AMENDED AND RESTATED 2021 OMNIBUS INCENTIVE PLAN

STOCK OPTION GRANT NOTICE AND AWARD AGREEMENT

Ensysce Biosciences, Inc., a Delaware corporation (the "Company"), pursuant to its 2021 Amended and Restated Omnibus Incentive Plan (the "Plan"), hereby grants to the individual listed below ("Participant") an option to purchase the number of shares of Common Stock (the "Shares") set forth below (the "Option"). The Option described in this Stock Option Grant Notice (the "Grant Notice") is subject to the terms and conditions set forth in the Award Agreement attached hereto as Exhibit A (the "Agreement") and the Plan, each of which is incorporated herein by reference. Unless otherwise defined herein, capitalized terms used in this Grant Notice and the Agreement will have the meanings defined in the Plan.

Participant:	David Tanzer
Grant Date:	February 14, 2022
Exercise Price Per Share:	$6.28
Total Number of Shares Subject to Option:	500,000
Expiration Date:	February 14, 2032
Type of Option:	☐ Incentive Stock Option (to the extent permitted by 422(d) of the Code) ☒ Non-Qualified Stock Option
Vesting Schedule:	Immediately vested
Termination:	This Option does not terminate and need not be exercised upon Participant ceasing to be engaged as a consultant to the Company but shall remain exercisable through the Expiration Date.

[Signature Page to Follow]

By signing below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and this Grant Notice. This document may be executed, including by electronic means, in multiple counterparts, each of which will be deemed an original, and all of which together will be deemed a single instrument.

ENSYSCE BIOSCIENCES, INC.

/s/ David Humphrey
Name: David Humphrey
Title: Chief Financial Officer

PARTICIPANT

/s/ David Tanzer
Name: David Tanzer

ACKNOWLEDGED AND AGREED

MERCURY FUNDINGCO, LLC

/s/ David Tanzer
Name: David Tanzer
Title: Managing Member

EXHIBIT A
TO STOCK OPTION GRANT NOTICE AWARD AGREEMENT

1. Award of Option. Effective as of the Grant Date set forth in the Grant Notice, the Company has granted to Participant the Option to purchase part or all of the aggregate number of Shares set forth in the Grant Notice, subject to the terms and conditions set forth in the Grant Notice, the Plan and this Agreement.

2. Term of Option. The Option may not be exercised later than the Expiration Date set forth in the Grant Notice, subject to earlier termination in accordance with the Plan and this Agreement.

3. Option Exercise Price. The exercise price per Share of the Option (the "Exercise Price") is set forth in the Grant Notice.

4. Vesting and Exercise of Option. Subject to the continued service of Participant with the Company through the relevant vesting dates, the Option shall become vested and exercisable in such amounts and at such times as set forth in the Grant Notice. In addition:

a. Effect of Termination of Service on the Option. Unless otherwise provided in the Grant Notice, this Agreement or any written employment agreement between Participant and the Company that expressly addresses treatment of stock option grants under the Plan, the termination or survival of the Option upon the Termination of Participant will be determined in accordance with Section 6.4 of the Plan.

b. Service with Affiliates. Solely for purposes of this Agreement, service with the Company will be deemed to include service with an Affiliate of the Company (for only so long as such entity remains an Affiliate of the Company).

c. Method of Exercise. Participant may exercise the Option only to the extent it is vested. To exercise the Option, Participant must give written notice of exercise to the Company specifying the number of shares of Common Stock to be purchased, accompanied by payment in full of the aggregate Exercise Price in accordance

with Section 6.3(d) of the Plan. Such notice must specify the date (not to exceed more than ninety (90) days after the date of such notice) on which the shares will be purchased and be accompanied by any further documents or instruments the Company deems necessary or desirable to carry out the purposes or intent of this Agreement.

d. Partial Exercise. The Option may be exercised in whole or in part, provided, however, that the minimum number of Shares with respect to which the Option may be exercised is one hundred (100). If less than one hundred (100) Shares remain outstanding under the Option at any time, the Option may only be exercised in whole. Any exercise may apply only with a whole number of Shares.

e. Conditions of Exercise. The Option may not be exercised, and any purported exercise will be void, if the issuance of Shares upon such exercise would constitute a violation of any law, regulation, or exchange listing requirement. The Committee may from time to time modify the terms of the Option or impose additional conditions on the exercise of the Option as it deems necessary or appropriate to facilitate compliance with any law, regulation or exchange listing requirement.

f. Rights as Stockholder. The Option will not confer upon Participant any of the rights or privileges of a stockholder in the Company unless and until Participant is issued Shares following Participant's exercise of the Option.

5. Non-Transferability of Option. Participant may not anticipate, alienate, attach, sell, assign, pledge, encumber, charge or otherwise transfer the Option other than by will or by the laws of descent and distribution. The Option shall be exercisable, during Participant's lifetime, only by Participant.

6. Adjustments. The Exercise Price, as well as the number and kind of shares subject to the Option, are subject to adjustment in accordance with Section 4.2 of the Plan.

7. No Continuation of Service. Neither the Plan nor this Agreement will confer upon Participant any right to continue in the employment or service of the Company or any of its Affiliates, or limit in any respect the right of the Company or its Affiliates to discharge Participant at any time, for any reason.

8. Withholding.

a. Regardless of any action the Company takes with respect to any or all income tax, payroll tax or other tax-related withholding ("Tax-Related Items"), Participant acknowledges that the ultimate liability for all Tax-Related Items owed by Participant is and remains Participant's responsibility and that the Company (i) makes no representations or undertakings regarding the treatment of any Tax- Related Items in connection with any aspect of the Option, including the grant, vesting or exercise of the Option or the subsequent sale of Shares acquired upon exercise; and (ii) does not commit to structure the terms of the grant or any aspect of the Option to reduce or eliminate Participant's liability for Tax-Related Items.

b. Prior to exercise of the Option, Participant shall pay or make adequate arrangements satisfactory to the Company to satisfy all withholding obligations of the Company. In this regard, Participant authorizes the Company to withhold all applicable Tax-Related Items legally payable by Participant from Participant's wages or other cash compensation paid to Participant by the Company or from proceeds of the sale of the Shares. Alternatively, or in addition, to the extent permissible under applicable law, the Company may (i) sell or arrange for the sale of Shares that Participant acquires to meet the withholding obligation for Tax-Related Items, and/or (ii) withhold Shares otherwise issuable upon exercise of the Option, provided that the Company only withholds the amount of Shares necessary to satisfy the withholding amount (not to exceed maximum statutory rates). Finally, Participant shall pay to the Company any amount of Tax-Related Items that the Company may be required to withhold as a result of Participant's participation in the Plan that cannot be satisfied by the means previously described. The Company may refuse to issue and deliver Shares upon exercise of the Option if Participant fails to comply with Participant's obligations in connection with the Tax-Related Items as described in this Section 8.

9. The Plan. A prospectus describing the Plan has been furnished to Participant. The Plan itself is available upon request, and its terms and provisions are incorporated herein by reference. Pursuant to the Plan, the Committee is authorized to construe and interpret the terms and provisions of the Plan and to adopt rules and regulations not inconsistent with the Plan as it deems necessary to carry the Plan into effect. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Committee with respect to questions arising under the Plan, the Grant Notice or this Agreement.

10. Company Policies. Participant agrees, in consideration for the grant of the Option, to be subject to any policies by the Company and its Affiliates regarding compensation recapture (i.e., clawbacks), securities trading, and hedging or pledging of securities that may be in effect from time to time, or as may otherwise be required by applicable law, regulation or exchange listing standard.

11. Entire Agreement. The Grant Notice and this Agreement, together with the Plan, represent the entire agreement between the parties with respect to the subject matter hereof and supersede any prior agreement, written or otherwise, relating to the subject matter hereof.

12. Amendment. This Agreement may only be amended by a writing signed by each of the parties hereto; provided that the Company may amend this Agreement without Participant's consent, if the amendment does not impair Participant's rights hereunder or as otherwise permitted in Section 4.e above.

13. Governing Law. This Agreement will be construed in accordance with the laws and judicial decisions of the State of Delaware, without regard to the application of the principles of conflicts of laws.

14. Headings. The headings in this Agreement are for convenience only. They form no part of the Agreement and will not affect its interpretation.

15. Incentive Stock Options.

a. If the Option is designated as an Incentive Stock Option, Participant acknowledges that nonetheless a portion of the Option may not qualify (or may cease to qualify) as an "incentive stock option" under the Code due to limitations set forth in Section 422(d) of the Code or otherwise. To the extent the Option does not qualify for treatment as an "incentive stock option" under the Code, it will be treated as a Non-Qualified Stock Option. The Company does not guarantee any particular tax treatment for the Option or the Shares subject to the Option.

b. If the Option is designed as an Incentive Stock Option, Participant shall give prompt written notice to the Company of any disposition or other transfer of any Shares acquired under the Option, if such disposition or transfer is made (i) within two years from the Grant Date, or (ii) within one year after the transfer of such Shares to Participant. Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by Participant in such disposition or other transfer.

16. Electronic Delivery of Documents. Participant authorizes the Company to deliver electronically any prospectuses or other documentation related to the Option and any other compensation or benefit plan or arrangement in effect from time to time (including, without limitation, reports, proxy statements or other documents that are required to be delivered to participants in such arrangements pursuant to federal or state laws, rules or regulations). For this purpose, electronic delivery will include, without limitation, delivery by means of e-mail or e-mail notification that such documentation is available on the Company's Intranet site. Upon written request, the Company will provide to Participant a paper copy of any document also delivered to Participant electronically. The authorization described in this paragraph may be revoked by Participant at any time

by written notice to the Company.

17. Further Assurances. Participant agrees, upon demand of the Company or the Committee, to do all acts and execute, deliver and perform all additional documents, instruments and agreements which may be reasonably required by the Company or the Committee, as the case may be, to implement the provisions and purposes of this Agreement and the Plan.

18. Restrictive Covenants. To the extent allowed by and consistent with applicable law and any applicable limitations period, if it is determined at any time that Participant has materially breached any employment-related covenants, the Company will be entitled to cause any unvested portion of the Option to be immediately cancelled without any payment of consideration by the Company.

Exhibit 21.1

Subsidiaries of Ensysce Biosciences, Inc.

Legal Entity	Jurisdiction of Organization
Covistat, Inc. (79.2%)	Delaware
EBI OpCo, Inc.	Delaware
EBI Operating, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-262419 and 333-260116 on Form S-8 of our report dated March 31, 2022 (which report includes an explanatory paragraph regarding the existence of substantial doubt about the Company's ability to continue as a going concern), relating to the consolidated financial statements of Ensysce Biosciences, Inc. as of December 31, 2021 and 2020 and for each of the two years in the period ended December 31, 2021, included in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
March 31, 2022

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lynn Kirkpatrick, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ensysce Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2022

By: */s/ Lynn Kirkpatrick*
Lynn Kirkpatrick
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Humphrey, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ensysce Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2022

By: */s/ David Humphrey*
David Humphrey
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Ensysce Biosciences, Inc. (the "Company") on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission (the "Report"), I, Lynn Kirkpatrick, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as added by §906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the period covered by the Report.

Date: March 31, 2022

By: */s/ Lynn Kirkpatrick*
Lynn Kirkpatrick
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Ensysce Biosciences, Inc. (the "Company") on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission (the "Report"), I, David Humphrey, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as added by §906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the period covered by the Report.

Date: March 31, 2022

By: */s/ David Humphrey*
David Humphrey
Chief Financial Officer
(Principal Financial Officer)