As filed with the Securities and Exchange Commission on November 16, 2022

Registration No. 333-268038

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

AMENDMENT NO. 1 TO
FORM S-1
REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

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

Delaware	**2834**	**82-2755287**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

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(858) 263-4196
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the 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 ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark 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 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the SEC, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. The securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion. Dated November 16, 2022.

PRELIMINARY PROSPECTUS

ENSYSCE BIOSCIENCES, INC.

5,274,261 Shares of Common Stock
Pre-Funded Warrants to Purchase up to 5,274,261 Shares of Common Stock
Series A Warrants to Purchase up to 5,274,261 Shares of Common Stock
Series B Warrants to Purchase up to 5,274,261 Shares of Common Stock

We are offering 5,274,261 shares of our common stock and warrants to purchase shares of common stock, based on an assumed combined public offering price of $2.37 per share and accompanying warrants (the last reported sale price of our common stock on Nasdaq on November 14, 2022). Each share of our common stock is being sold together with a five-year warrant to purchase one share of our common stock (a "*Series A warrant*") and a six-month warrant to purchase one share of our common stock (a "*Series B warrant*"). The warrants will have an exercise price of $ per share (100% of the combined public offering price per share of common stock and accompanying warrants) and will be exercisable upon issuance. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants.

We are also offering to those investors, if any, whose purchase of shares of our common stock in this offering would result in such investor, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the investor, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of the common stock that would otherwise result in the investor's beneficial ownership exceeding 4.99% (or, at the election of the investor, 9.99%), pre-funded warrants each to purchase one share of our common stock at an exercise price of $0.0001, which we refer to as the pre-funded warrants. Each pre-funded warrant will be exercisable upon issuance and will expire when exercised in full. Each pre-funded warrant is being sold with a Series A warrant and a Series B warrant. The public offering price for each pre-funded warrant and the accompanying warrants is equal to the price per share of common stock and the accompanying warrants being sold to the public in this offering, minus $0.0001. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the pre-funded warrants.

For each pre-funded warrant we sell, the number of shares of common stock we sell in this offering will be decreased on a one-for-one basis. The shares of common stock and/or pre-funded warrants and the accompanying warrants can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance. You should read this prospectus carefully before you invest in our securities.

Our common stock is listed on the Nasdaq Capital Market, or Nasdaq, under the symbol "*ENSC*" and certain warrants we previously issued (the "*Public Warrants*") are quoted on the OTC Pink Open Market under the symbol "*ENSCW*." On November 14, 2022, the closing sale price of our common stock as reported on Nasdaq was $2.37 and the closing bid price for our Public Warrants as quoted on the OTC Pink Open Market was $0.0334. There is no established public trading market for the pre-funded warrants or the warrants, and we do not expect such a market to develop. We do not intend to apply to list the pre-funded warrants or the warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants and the warrants will be limited. Certain information in this prospectus is based on an assumed combined public offering price of $2.37 per share and accompanying warrants (the last reported sale price of our common stock on Nasdaq on November 14, 2022). The actual combined public offering price per share and accompanying warrants and the actual combined public offering price per pre-funded warrant and accompanying warrants will be determined between us and the underwriter based on market conditions at the time of pricing, and may be at a discount to the current market price of our common stock.

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended, and, as such, have elected to comply with certain reduced disclosure and regulatory requirements.

Our business and investing in our securities involves a high degree of risk. See "*Risk Factors*" beginning on page 7 of this prospectus.

	Per Share and Accompanying Warrants	Per Prefunded Warrant and Accompanying Warrants	Total
Price to the public	$	$	$
Underwriting discounts and commissions(1)	$	$	$
Proceeds to us (before expenses)	$	$	$

(1) See "*Underwriting*" beginning on page 119 for additional information regarding the compensation payable to the underwriter.

We have granted the underwriter an option to purchase up to 791,139 additional shares of common stock and/or Series A warrants and/or Series B warrants, in any combinations thereof. The purchase price to be paid by the underwriter per additional share of common stock will be $, less underwriting discounts and commissions, the purchase price to be paid by the underwriter per additional Series A warrant will be $0.01, less underwriting discounts and commissions, and the purchase price to be paid by the underwriter per additional Series B warrant will be $0.01, less underwriting discounts and commissions. If the underwriter exercises the option in full, the total underwriting discounts and commissions payable by us will be $, and the total proceeds to us, before expenses, will be approximately $. The underwriter may exercise this option at any time or from time to time, in whole or in part, during the 45-day period from the date of this prospectus. See "*Underwriting*" on page 119 of this prospectus for a description of the over-allotment option.

Certain of our existing stockholders, including certain affiliates of our directors, have indicated an interest in purchasing an aggregate of approximately $500,000 of securities in this offering at the combined public offering price per share and accompanying warrants set forth above. However, because indications of interest are not binding agreements or commitments to purchase, the underwriter may determine to sell more, less or no securities in this offering to any of these stockholders, or any of these stockholders may determine to purchase more, less or no securities in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriter expects to deliver the shares, pre-funded warrants and warrants to investors against payment on or about , 2022.

Lake Street

The date of this prospectus is , 2022.

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FREQUENTLY USED TERMS

Unless otherwise stated in this registration statement/prospectus or the context otherwise requires, references to:

Definitions:	
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
2022 Notes	The senior secured convertible promissory notes in the aggregate original principal amount of $8.48 million, sold in two closings on June 30, 2022 and August 8, 2022, respectively, pursuant to the Securities Purchase Agreement entered into on June 30, 2022
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
AUC	Area under the concentration time curve
Board	Board of directors of Ensysce, or a committee thereof, as applicable
Business Combination	The definitive merger agreement among LACQ, Merger Sub and Former Ensysce, dated January 31, 2021, providing for, among other things, and subject to terms and conditions therein, the business combination between LACQ and Former Ensysce pursuant to the merger of Merger Sub with and into Former Ensysce, with Former Ensysce continuing as the surviving entity and as a wholly-owned subsidiary of LACQ
CARA	Comprehensive Addiction and Recovery Act
CDC	Center for Disease Control

Definitions:	
CDER	Center for Drug Evaluation and Research
cGMP	Current Good Manufacturing Practice
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
COVID-19	Novel coronavirus disease
Covistat	A subsidiary renamed EBIR, Inc.
CROs	Contract research organizations
CSA	Controlled Substances Act
CSOS	Controlled Substance Ordering System
DEA	United States Drug Enforcement Agency

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.
EBIR	Previously known as Covistat, Inc., EBIR, Inc. is 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
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, as amended
FDA	United States Food and Drug Administration
FDC Act	Federal Food, Drug and Cosmetic Act, as amended
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	55,306 shares of common stock that may be issued upon the exercise of warrants issued to GYBL under the terms of the GEM Agreement at an exercise price of $3.28 per share immediately prior to this offering
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
Investor Notes	The 2021 Notes and the 2022 Notes, collectively.
IRB	Institutional Review Board
JOBS Act	Jumpstart Our Business Startups Act of 2012
LACQ	Leisure Acquisition Corp., a Delaware Corporation
LACQ Warrants	Warrants that relate to the Business Combination or were issued prior to it and are exercisable for 445,063 shares of our common stock at a weighted average exercise price of $228.31 per share
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	The 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
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

Definitions:	
Prior Warrants	Warrants issued pursuant to the Securities Purchase Agreement. The Prior Warrants issued in (i) 2021 are exercisable for an aggregate of 54,174 shares of our common stock at an exercise price of $15.60 per share and (ii) 2022 are exercisable for an aggregate of 466,788 shares of our common stock at an exercise price of $14.17 per share
PTA	Patent Term Adjustment
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 500,000 shares of our common stock at an exercise price of $230.00 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
Securities Act	Securities Act of 1933, as amended
Securities Purchase Agreement	The Securities Purchase Agreement, dated as of September 24, 2021 or June 30, 2022, as the context dictates, by and between Ensysce and the institutional investors party thereto
Signature	Signature Therapeutics Inc.
SPA	A Securities Purchase Agreement, dated as of September 24, 2021 or June 30, 2022, as the context dictates, by and between Ensysce and the institutional investors party thereto
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

ABOUT THIS PROSPECTUS

Neither we nor the underwriter have authorized anyone to provide you with information other than that contained in this prospectus. We and the underwriter take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriter are offering to sell, and seeking offers to buy, these securities only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front cover page of this prospectus, or other earlier date stated in this prospectus, regardless of the time of delivery of this prospectus or of any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since those dates. This prospectus contains market data and industry statistics and forecasts that are based on independent industry publications and other publicly available information. Although we believe these sources are reliable, we do not guarantee the accuracy or completeness of this information and we have not independently verified this information. In addition, the market and industry data and forecasts that may be included in this prospectus may involve estimates, assumptions and other risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "*Risk Factors*" contained in this prospectus. Accordingly, investors should not place undue reliance on this information.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our securities or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to those jurisdictions.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under "*Where You Can Find More Information.*"

We own or have rights to trademarks, trade names and service marks that we use in connection with the operation of our business. In addition, our name, logos and website name and address are our trademarks or service marks. Solely for convenience, in some cases, the trademarks, trade names and service marks referred to in this prospectus are listed without the applicable ®, ™ and SM symbols, but we will assert, to the fullest extent under applicable law, our rights to these trademarks, trade names and service marks. Other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

On June 30, 2021, we consummated the transactions contemplated by the Merger Agreement, with the Company surviving in the Merger. In connection with the consummation of the Business Combination Transactions, LACQ changed its name to "Ensysce Biosciences, Inc."

On October 28, 2022, we effected a one-for-twenty reverse split of our common stock (the "*Reverse Split*"). All share and per share information has been restated retroactively, giving effect to the Reverse Split for all periods presented.

Unless the context indicates otherwise, references in this prospectus to the "*Company*," "*Ensysce*," "*we*," "*us*," "*our*," and similar terms refer to Ensysce Biosciences, Inc. (f/k/a Leisure Acquisition Corp.) and its consolidated subsidiaries.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes statements that express our 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 registration statement/prospectus 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 we operate. Such forward-looking statements are based on available current market material and management's expectations, beliefs and forecasts concerning future events impacting our company. Factors that may impact such forward-looking statements include:

- the risk that our lead product candidate PF614 and PF614-MPAR™ may not be successful in limiting or impeding abuse, overdose, or misuse or providing additional safety upon commercialization;
- reliance by us on third-party contract research organizations, or CROs, for our research and development activities and clinical trials;
- the need for substantial additional funding to complete the development and commercialization of our product candidates;
- the risk of additional dilution from repayment of the Investor Notes in common stock or re-setting the conversion price of the Investor Notes or reduced proceeds from a reduction in the exercise price of the Prior Warrants;
- the risk that our clinical trials may fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties;

- the risk that the potential product candidates that we develop 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 registration statement/prospectus;
- the risk that we will be unable to successfully market or gain market acceptance of our product candidates;
- the risk that our product candidates may not be beneficial to patients or successfully commercialized;
- the risk that we have 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 we depend for laboratory, clinical development, manufacturing, and other critical services will fail to perform satisfactorily;
- the risk that our 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 we 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 our management team;
- changes in our regulatory environment;
- the ability to attract and retain key scientific, medical, commercial, or management personnel;
- changes in our industry;
- our ability to remediate any material weaknesses or maintain effective internal controls over financial reporting;
- the risk that our common stock will be delisted from Nasdaq;
- The risk that we may not be able to regain or maintain compliance with applicable listing standards of Nasdaq;
- potential litigation associated with the Business Combination Transactions;
- other factors disclosed in this prospectus; and
- other factors beyond our control.

The forward-looking statements contained in this prospectus are based on our current expectations and beliefs concerning future developments and their potential effects on our company. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our 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*" in this prospectus. 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. We 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.

PROSPECTUS SUMMARY

The following summary highlights certain information described in greater detail elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider or that may be important to you in making an investment decision. You should carefully read the entire prospectus, including the information under, "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements included elsewhere in this prospectus, before making an investment in our securities. You should carefully read this entire prospectus.

The Company

We are a clinical stage pharmaceutical company seeking to develop innovative solutions for severe pain relief while reducing the potential for opioid misuse, abuse and overdose. Prescription opioid abuse presents 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. 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.

Our current development pipeline includes two new drug platforms: (1) an abuse-resistant opioid prodrug technology – theTrypsin Activated Abuse Protection, or the TAAP platform; and (2) 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 chronic pain while reducing the human and economic costs associated with prescription opioid drug abuse. 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.

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 di-mesylate ("*nafamostat*") to inhibit the action of enzymes associated with the COVID-19 infection, and have done preliminary work on

the development of an oral and inhalation drug product of nafamostat, for use against coronaviral infections and other pulmonary diseases such as cystic fibrosis.

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 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 prospectus or the registration statement of which it forms a part.

Implications of Being an Emerging Growth Company

As a company with less than $1.235 billion in revenues during our last completed fiscal year, we qualify as an "*emerging growth company*" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements that are otherwise applicable generally to public companies. These reduced reporting requirements include:

- an exemption from compliance with the auditor attestation requirement on the effectiveness of our internal control over financial reporting;
- an exemption from compliance with any requirement that the Public Company Accounting Oversight Board may adopt regarding a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure about our executive compensation arrangements; and
- an exemption from the requirements to obtain a non-binding advisory vote on executive compensation or a stockholder approval of any golden parachute arrangements.

We have elected to take advantage of some, but not all, of the available benefits under the JOBS Act. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Further, pursuant to Section 107 of the JOBS Act, as an emerging growth company, we have elected to use the extended transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. As a result, our consolidated financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make our common stock less attractive to investors.

We will remain an emerging growth company until the earliest to occur of: (i) the end of the first fiscal year in which our annual gross revenues are $1.235 billion or more; (ii) the end of the first fiscal year in which we are deemed to be a "*large accelerated filer*," as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act; (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities; and (iv) December 31, 2025.

THE OFFERING

The following summary contains basic information about this offering. The summary is not intended to be complete. You should read the full text and more specific details contained elsewhere in this prospectus.

Issuer:	Ensysce Biosciences, Inc.
Common stock offered:	5,274,261 shares (assuming a combined public offering price of $2.37 per share and accompanying warrants (the last reported sale price of our common stock on Nasdaq on November 14, 2022)).
Pre-funded warrants offered:	We are also offering to those investors, if any, whose purchase of shares of our common stock in this offering would result in such investor, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the investor, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of the common stock that would otherwise result in the investor's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%), pre-funded warrants each to purchase one share of our common stock at an exercise price of $0.0001, which we refer to as pre-funded warrants. Each pre-funded warrant will be exercisable upon issuance and will expire when exercised in full. Each pre-funded warrant is being sold with a Series A warrant and a Series B warrant. The combined public offering price for each pre-funded warrant and accompanying warrants is equal to the combined public offering price per share of common stock and accompanying warrants being sold in this offering, minus $0.0001. For each pre-funded warrant we sell, the number of shares of common stock we sell will be decreased on a one-for-one basis. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the pre-funded warrants. See "*Description of Securities We Are Offering*" for additional information.
Warrants offered:	Each share of common stock or pre-funded warrant is being offered together with a five-year Series A warrant to purchase one share of our common stock and a six-month Series B warrant to purchase one share of our common stock. The warrants will have an exercise price of $ per share (100% of the combined public offering price per share of common stock and accompanying warrants) and will be exercisable upon issuance. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants See "*Description of Capital Stock*" for additional information.

Common stock to be outstanding after this offering: 8,115,352 shares, assuming we sell only shares of common stock and no pre-funded warrants and assuming no exercise of the warrants (assuming a combined public offering price of $2.37 per share and accompanying warrants (the last reported sale price of our common stock on Nasdaq on November 14, 2022) (or 8,906,491 shares if the underwriter's option to purchase additional securities is exercised in full).

Underwriter's option to purchase additional securities[2]: We have granted the underwriter an option to purchase up to 791,139 additional shares of common stock and/or Series A warrants and/or Series B, or any combination thereof. The purchase price to be paid by the underwriter per additional share of common stock will be $, less underwriting discounts and commissions, the purchase price to be paid by the underwriter per additional Series A warrant will be $0.01, less underwriting discounts and commissions and the purchase price to be paid by the underwriter per additional Series B warrant will be $0.01, less underwriting discounts and commissions.

[2] Because the warrants are not listed on a national securities exchange or other nationally recognized trading market, the underwriter will be unable to satisfy any over-allotment of shares and warrants without exercising the underwriter's over-allotment option with respect to the warrants. As a result, the underwriter has informed us that it intends to exercise its over-allotment option for all of the warrants which are over-allotted, if any, at the time of the initial offering of the shares and the warrants. However, because our common stock is publicly traded, the underwriter may satisfy some or all of the over-allotment of shares of our common stock, if any, by purchasing shares in the open market and will have no obligation to exercise the over-allotment option with respect to our common stock. If the underwriter exercises its over-allotment option with respect to the warrants in full, but does not exercise its over-allotment option with respect to our common stock, then the effective warrant coverage for each share of common stock sold in this offering would be 230% instead of the 200% stated on the cover page of this prospectus.

Use of Proceeds: We estimate that the net proceeds from the offering will be approximately $11.3 million, assuming we sell only shares of common stock and no pre-funded warrants and assuming no exercise of the warrants, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriter exercises its over-allotment option to purchase additional securities in full, we estimate that the net proceeds from this offering will be approximately $13.0 million, assuming we sell only shares of common stock and no pre-funded warrants and assuming no exercise of the Series A warrants or Series B warrants, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each holder of the 2022 Notes has the right to require us to use 20% of the net proceeds from this offering to reduce the balance of such holder's 2022 Note, on a pro rata basis. Subject to any such reduction in the balance of the 2022 Notes, we intend to use these net proceeds to further the clinical development of our product candidates, and for working capital and other general corporate purposes. See "*Use of Proceeds*" in this prospectus.

Ticker Symbol: Our common stock is listed on the Nasdaq under the symbol "*ENSC*," and our Public Warrants are listed on the OTC Pink Open Market under the symbol "*ENSCW*." There is no established public trading market for the pre-funded warrants or the warrants, and we do not expect such a market to develop. We do not intend to apply to list the pre-funded warrants or the warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants and the warrants will be limited.

Risk Factors: See "*Risk Factors*" and other information included in this prospectus for a discussion of factors you should consider before investing in our securities.

The number of shares of common stock to be outstanding after the offering is based on 2,841,091 shares of common stock outstanding as of November 14, 2022, and excludes, as of that date, the following:

- 520,962 shares issuable upon the exercise of the Prior Warrants, with a weighted-average exercise price of $3.75 per share, assuming a combined public offering price of $2.37 per share and accompanying warrants (the last reported sale price of our common stock on Nasdaq on November 14, 2022);
- 500,000 shares issuable upon the exercise of the Public Warrants, with a weighted-average exercise price of $230.00 per share;
- 445,063 shares issuable upon the exercise of the LACQ Warrants, with a weighted-average exercise price of $228.31 per share;
- 55,306 shares issuable upon the exercise of the GEM Warrants, with a weighted-average exercise price of $2.37 per share, assuming a combined public offering price of $2.37 per share and accompanying warrants (the last reported sale price of our common stock on Nasdaq on November 14, 2022);
- 10,548,522 shares issuable upon the exercise of Series A warrants and Series B warrants sold in this offering (assuming a combined public offering price of $2.37 per share and accompanying warrants) (the last reported sale price of our common stock on Nasdaq on November 14, 2022);

- 2,594,092 shares issuable upon conversion of the 2022 Notes (assuming a combined public offering price of $2.37 per share and accompanying warrants) (the last reported sale price of our common stock on Nasdaq on November 14, 2022);
- 321,744 shares issuable upon exercise of stock options outstanding under our 2021 Omnibus Incentive Plan;
- 12,750 shares issuable upon vesting of restricted stock units, or RSU's, outstanding under our 2021 Omnibus Incentive Plan; and
- 49,092 shares reserved for future issuance under our 2021 Omnibus Incentive Plan.

On October 28, 2022, we effected a one-for-twenty reverse split of our outstanding Common Stock (the "*Reverse Split*"). Unless the context otherwise indicates, all share and per share amounts in this prospectus have been retroactively restated to reflect the Reverse Split.

Unless expressly indicated or the context requires otherwise, all information in this prospectus assumes no (i) no purchaser elects to purchase pre-funded warrants, (ii) no exercise of the warrants offered hereby and (iii) exercise of the underwriter's option to purchase additional securities.

Certain of our existing stockholders, including certain affiliates of our directors, have indicated an interest in purchasing an aggregate of approximately $500,000 of securities in this offering at the combined public offering price per share and accompanying warrants. However, because indications of interest are not binding agreements or commitments to purchase, the underwriter may determine to sell more, less or no securities in this offering to any of these stockholders, or any of these stockholders may determine to purchase more, less or no securities in this offering.

Risk Factor Summary

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under the section titled "*Risk Factors*" beginning on page **7** of this prospectus. The below summary is qualified in its entirety by that more complete discussion of such

risks and uncertainties. If we are unable to adequately address these and other risks we face, our business, results of operations, financial condition and prospects may be harmed. 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. 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 must obtain regulatory approval and fulfill numerous other requirements to be successful.
- We require substantial additional funding.
- We may incur additional dilution from repayment of the Investor Notes in common stock or re-setting the conversion price of the Investor Notes or reduced proceeds to Ensysce from a reduction in the exercise price of the Prior Warrants;
- 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.
- 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.
- Our employees or others on which our business depends may engage in misconduct or other improper activities.
- 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, for management of moderate to severe chronic pain when a continuous, around-the-clock analgesic is needed for an extended period of time, may not lead to a faster development or regulatory review or approval process and does not assure FDA approval.
- 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 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 intellectual property agreements with third parties may be subject to disagreements.
- Intellectual property rights do not necessarily address all potential threats to our business.
- 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, 2021and 2020.
- Nasdaq may delist our common stock and/or our Public Warrants may not continue to trade on the OTC Pink Open Market; during most of the period since June 2022 we have not met the listing requirements for Nasdaq.
- If you purchase securities in this offering, you will suffer immediate dilution of your investment.
- Our management will have broad discretion in the use of the net proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not yield a return.

MARKET AND INDUSTRY DATA AND FORECASTS

We obtained the industry and market data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies, publicly available information and research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In addition, while we believe the industry and market data included in this prospectus is reliable and based on reasonable assumptions, such data involve material risks and other uncertainties and are subject to change based on various factors, including those discussed in the section entitled "*Risk Factors*." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the following risk factors, together with all of the other information included in this registration statement/prospectus, before making an investment decision. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have an adverse effect on our business, cash flows, financial condition and results of operations. You should also carefully consider the following risk factors in addition to the other information included in this registration statement/prospectus, including matters addressed in the section entitled "Cautionary Note Regarding Forward-Looking Statements." We may face additional risks and uncertainties that are not presently known to us or that we currently deem immaterial, which may also impair our business or financial condition.

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 $18.7 million for the nine months ended September 30, 2022 and $29.1 million for the year ended December 31, 2021. As of September 30, 2022, we had an accumulated deficit of $105.4 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 and net proceeds from the offering will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2023, while advancing our main product candidates such as, PF614 and PF614 MPAR™ and nafamostat through their respective next phases of 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 Investor Notes with common stock.

Under the terms of the Securities Purchase Agreement, we are permitted to repay principal and interest on the Investor Notes by issuing additional shares of common stock. In addition, the conversion price of the Investor Notes, and the exercise price of the Prior Warrants, are subject to downward revision in the event we make certain issuances of our common stock at prices below the conversion price. The conversion price of the 2022 Notes and exercise price of the Prior Warrants will be reset to the price our shares are sold in this offering, but not below a price of $2.006 for the Prior Warrants issued in 2022 or $15.60 for the Prior Warrants issued in 2021. In such case, stockholders will have dilution in amounts exceeding the straight conversion of the Investor Notes or, with respect to the Prior Warrants, the Company will receive a reduced level of proceeds from the exercise of the Prior Warrants. Please see the discussion of conversion and exercise prices under "*Description of Capital Stock—Convertible Promissory Notes" and "—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.

Under a Share Purchase Agreement between us, GEM Global Yield LLC SCS ("*GEM Global*") and GEM Yield Bahamas Limited ("*GYBL*"), dated as of December 29, 2020, including a Registration Rights Agreement between the same parties and dated as of the same date (the "*GEM Agreement*"), we are entitled to draw down up to $60 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 equity line 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 pursuant to the GEM Agreement, 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, 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, of which $800,000 was satisfied with 46,062 shares of common stock transferred from related parties in July 2022 and (ii) the issuance of a warrant granting GYBL the right to purchase 55,306 shares of our common stock, at a strike price per share prior to the offering described in this prospectus of $3.28. 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 strike price, previously reset, will be reset to the offering price for our common stock in the offering.

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.

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. To date, we have not used the GEM facility to raise capital.

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. Part A of the study completed enrollment in December 2021 and Part B was completed mid-year 2022. 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 PF614, 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 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 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 companies developing novel non-opioid pain drug candidates such as pharmaceutical companies and 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. 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 seven full-time employees and five 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*") now known as Societal CDMO, ("*Societal*") 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 *Societal*, if and when any of our product candidates are approved for commercialization. In the event that*Societal* is unable to perform its obligations under the Recro Agreement, we may be unable to replace the *Societal* 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 *Societal*, 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 *Societal*, 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 *Societal*, 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 *Societal*, 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 following direct injection, and the Phase 1 trial we have conducted with TAAP prodrug PF614 ("*prodrug*": a medication or compound that, after administration, is metabolized, i.e., converted within the body into a pharmacologically active drug), demonstrated that, after oral administration, 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.

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 (such as the clinical hold placed on PF614-MPAR in January 2021), 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 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 for chronic pain 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 for management of moderate to severe chronic pain when a continuous, around-the-clock analgesic is needed for an extended period of time. We believe that fast track designation 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 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 may 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). 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.

FDA's evolving standards for the approval of opioid products may delay or prevent approval of our product candidates.

FDA has identified addressing misuse and abuse of opioid drugs as one of its highest priorities. As part of its plan, the agency has established new standards for the development of prescription opioids with abuse-deterrent formulations and has published two sets of guidance. Since the publication of the second guidance in November 2017, FDA has not approved any new abuse–deterrent opioid drugs. If we are unable to meet FDA's new and evolving standards for approving opioid products, we will not be able to market our products.

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 will expire in the next nine years. In addition, certain of our patents relating to the use of nafamostat for treating respiratory diseases will expire in the next seven 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 natural expiration of a utility 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 those countries, 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 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, Ltd. ("*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 has caused, and may in the future 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.

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.

To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities as we have done in the past, our stockholders' ownership interest has been, and may in the future 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 Investor Notes in common stock or re-setting the conversion price of the Investor Notes if we issue equity at a price below the conversion price of the Investor Notes. Also, we will receive reduced proceeds if the exercise price of the Prior Warrants is reduced. The conversion price of the 2022 Notes and exercise price of the Prior Warrants issued in 2022 will be reset to the price our shares are sold in this offering, but not below a price of $2.006. The exercise price of the Prior Warrants issued in 2021 may be reset to the price our shares are sold in this offering, but not below a price of $15.60.

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. 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. The Investor Notes contain such restrictions.

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.

In addition, any issuances of common stock pursuant to the GEM Agreement would result in dilution of the ownership interest of our shareholders. Any such issuances may also have a negative impact on the market price of our common stock because of the discount at issuance. Strike price resets of the GEM Warrants would also dilute our shareholders. 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, 2020 and 2019, 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 are taking 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 Business Combination, 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 are not 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 this Offering, 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.

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 exercisable for an aggregate of approximately 500,000 shares of our common stock with an exercise price of $230.00 per share. There are LACQ Warrants exercisable for an aggregate of approximately 445,063 shares of our common stock with a weighted average exercise price of $228.31 per share. In addition, there are GEM Warrants exercisable for 55,306 shares of our common stock (subject to possible adjustment for anti-dilution events) with an exercise price of $3.28 per share. There are also Prior Warrants from 2021 exercisable for an aggregate of approximately 54,174 shares of our common stock (subject to possible adjustment for anti-dilution events) with an exercise price of $15.60 per share. In addition, Prior Warrants from 2022 are exercisable for an aggregate of approximately 466,788 shares of our common stock (subject to possible adjustment for anti-dilution events) with an exercise price of $14.17 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.

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 Investor 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 have granted equity awards to employees, directors, and consultants under our 2021 Omnibus Incentive Plan and plan to do so in the future. We have used, and may in the future use, our common stock to make repayment of some or all of the principal and interest on the Investor 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.

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. Our common stock has been trading on Nasdaq at less than $1.00.

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 failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.

Our common stock is currently listed for trading on The Nasdaq Capital Market. We must satisfy the continued listing requirements of Nasdaq, to maintain the listing of our common stock on The Nasdaq Capital Market. A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities.

On June 16, 2022, we received written notice (the "*Notice*") from Nasdaq that our Minimum Value of Listed Securities ("*MVLS*") was below the minimum of $35 million required for continued listing. We have until December 13, 2022, to regain compliance. To regain compliance, the MVLS must close at $35 million or more for a minimum of ten consecutive business days (or such longer period of time Nasdaq may require) during the compliance period ending December 13, 2022. The Company could also regain compliance by meeting the continued listing standard of a minimum stockholders' equity of at least $2.5 million, which standard the Company does not meet currently. If compliance is not regained by December 13, 2022, Nasdaq will provide written notice that our securities are subject to delisting. At that time, we may appeal any such delisting determination to a Nasdaq hearings panel.

On June 17, 2022, we received written notice from Nasdaq that we were not in compliance with the Nasdaq requirement for the bid price for our common stock to be at least $1.00 per share (the "*Deficiency Letter*"). We had until December 14, 2022, for the bid price for our common stock to close at $1.00 per share or more (the "*Minimum Bid Price*") for a minimum of 10 consecutive business days during the compliance period ending December 14, 2022 (or such longer period of time Nasdaq may require). If we did not regain compliance by December 14, 2022, Nasdaq staff would have provided notice that our securities were subject to delisting. We effected the Reserve Split to regain compliance with the Minimum Bid Price requirement. On November 11, 2022, we received written notice from Nasdaq that we had regained compliance with the Minimum Bid Price requirement. However, no assurance can be given that will be able to sustain compliance with the Minimum Bid requirement.

If our common stock were delisted from Nasdaq, trading of our common stock would most likely take place on an over-the-counter market established for unlisted securities, such as the OTCQB or the Pink Market maintained by OTC Markets Group Inc. An investor would likely find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors would likely not buy or sell our common stock due to difficulty in accessing over-the-counter markets, policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our common stock would be subject to SEC rules as a "*penny stock*," which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to the investor of penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher-priced stock, would further limit the ability of investors to trade in our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified employees and to raise capital.

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 October 31, 2022, our executive officers and directors beneficially owned approximately 26.2% of our common stock. These stockholders, acting together, may be able to significantly affect 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.

If you purchase securities in this offering, you will suffer immediate dilution of your investment.

You will incur immediate and substantial dilution as a result of this offering. The combined public offering price per share of common stock and accompanying warrants and the combined public offering price per pre-funded warrant and accompanying warrants will be substantially higher than the as adjusted net tangible book value per share of our common stock after giving effect to this offering. Therefore, if you purchase securities in this offering, you will pay an effective price per share of common stock you acquire that substantially exceeds our net tangible book value per share after this offering. Based on an assumed public offering price of $2.37 per share of common stock and accompanying warrants (the last reported sale price of our common stock on Nasdaq on November 14, 2022), and assuming no sale of any pre-funded warrants in this offering, no exercise of the warrants being offered in this offering, that no value is attributed to such warrants and that such warrants are classified as and accounted for as equity, you will

experience immediate dilution of $1.72 per share, representing the difference between our as adjusted net tangible book value per share after giving effect to this offering and the assumed public offering price per share and accompanying warrants.

Our management will have broad discretion in the use of the net proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not yield a return.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled "*Use of Proceeds*," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary from their currently intended use. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in investment-grade, interest-bearing securities. These investments may not yield a favorable return to our securityholders.

There is no public market for the pre-funded warrants or the warrants offered by us.

There is no established public trading market for the pre-funded warrants or the warrants, and we do not expect such a market to develop. In addition, we do not intend to apply to list the pre-funded warrants or the warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants and the warrants will be limited.

Holders of pre-funded warrants or warrants purchased in this offering will have no rights as common stockholders until such holders exercise their pre-funded warrants or warrants and acquire our common stock.

Until holders of the pre-funded warrants or warrants acquire shares of our common stock upon exercise thereof, such holders will have no rights with respect to the shares of our common stock underlying the pre-funded warrants or the warrants. Upon exercise of the pre-funded warrants or warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

The warrants are speculative in nature.

The warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Moreover, following this offering, the market value of the warrants, if any, will be uncertain and there can be no assurance that the market value of the warrants will equal or exceed their imputed offering price. The warrants will not be listed or quoted for trading on any market or exchange. There can be no assurance that the market price of our common stock will ever equal or exceed the exercise price of the warrants, and consequently, the warrants may expire valueless.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the shares of our common stock, pre-funded warrants and warrants in this offering will be approximately $11.3 million, or $13.0 million if the underwriter exercises its option to purchase additional securities in full, in each case, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and assuming no sale of any pre-funded warrants and no exercise of the warrants. We will receive additional proceeds of approximately $25.0 million if the warrants are exercised in full for cash based on the assumptions above.

Each holder of the 2022 Notes has the right to require us to use 20% of these net proceeds to reduce the balance of such holder's 2022 Notes, on a pro rata basis. Subject to any such reduction in the balance of the 2022 Notes, we currently intend to use these net proceeds for the further clinical development of our product candidates and for working capital and other general corporate purposes.

The 2022 Notes accrue interest at the rate of 6.0% per annum and were issued with an original issue discount of 6.0%. Of the aggregate $8.48 million of principal, $4.24 million matures on December 29, 2023 and $4.24 million matures on February 7, 2024. We are required to use the net proceeds from the sale of the 2022 Notes for working capital purposes.

The amounts and timing of our actual expenditures will depend upon numerous factors, including our clinical development efforts, our operating costs and the other factors described under "*Risk Factors*" in this prospectus. Accordingly, our management will have flexibility in applying the net proceeds from this offering. An investor will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds.

DILUTION

If you invest in our securities, your ownership interest will be diluted to the extent of the difference between the combined public offering price per share of our common stock and accompanying warrants and the as adjusted net tangible book value per share of our common stock immediately after giving effect to this offering.

Our net tangible book deficit as of September 30, 2022 was approximately $6.4 million, or approximately $(2.91) per share of common stock. Our net tangible book deficit is the amount of our total tangible assets less our liabilities. Net tangible book deficit per share is our net tangible book deficit divided by the number of shares of common stock outstanding as of September 30, 2022.

After giving effect to the assumed sale of 5,274,261 shares of common stock and accompanying warrants in this offering at an assumed combined public offering price of $2.37 per share and accompanying warrants (the last reported sale price of our common stock Nasdaq on November 14, 2022), and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and assuming no sale of any pre-funded warrants in this offering, no exercise of the warrants being offered in this offering, that no value is attributed to such warrants and that such warrants are classified as and accounted for as equity, our as adjusted net tangible book value as of September 30, 2022 would have been approximately $4.9 million, or approximately $0.65 per share of common stock. This amount represents an immediate increase in as adjusted net tangible book value of $3.56 per share to our existing stockholders and an immediate dilution of $1.72 per share to investors participating in this offering. We determine dilution per share to investors participating in this offering by subtracting as adjusted net tangible book value per share after giving effect to this offering from the assumed combined public offering price per share and accompanying warrants paid by investors participating in this offering.

The following table illustrates this dilution to new investors on a per share basis:

Assumed combined public offering price per share and accompanying warrants			$	2.37
Net tangible book deficit per share as of September 30, 2022	$	(2.91)		
Increase in net tangible book value per share attributable to this offering		3.56		
As adjusted net tangible book value per share after giving effect to this offering				0.65
Dilution per share to new investors in this offering			$	1.72

In accordance with SEC rules, in the event that the actual combined public offering per share and accompanying warrants is more or less than the assumed combined public offering price of $2.37 per share and accompanying warrants (the last reported sale price of our common stock Nasdaq on November 14, 2022), the number of shares and/or pre-funded warrants and warrants we sell may be decreased or increased so long as the aggregate offering amount does not exceed the total amount registered on the registration statement of which this prospectus forms a part. Assuming a total offering amount of $12,500,000, for every $0.10 increase in the assumed combined public offering price per share and accompanying warrants, we would sell 213,533 fewer shares of common stock and/or pre-funded warrants and warrants and for every $0.10 decrease in the assumed combined public offering price per share and accompanying warrants, we would sell 232,346 additional shares of common stock and/or pre-funded warrants and warrants. Each $0.10 increase in the assumed combined public offering price per share and accompanying warrants would increase the as adjusted net tangible book value per share by $0.02 per share and increase the dilution per share to investors participating in this offering by $0.08 per share after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each $0.10 decrease in the assumed combined public offering price per share and accompanying warrants would decrease the as adjusted net tangible book value per share by $0.02 per share and decrease the dilution per share to investors participating in this offering by $0.08 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriter exercises its option to purchase additional securities in full, the as adjusted net tangible book value per share after giving effect to this offering would be approximately $0.80 per share, which represents an immediate increase in the as adjusted net tangible book value of $0.15 per share of our common stock to existing stockholders and an immediate dilution in the as adjusted net tangible book value of $1.57 per share of our common stock to new investors participating in this offering.

Because the warrants are not listed on a national securities exchange or other nationally recognized trading market, the underwriter will be unable to satisfy any over-allotment of shares and warrants without exercising the underwriter's over-allotment option with respect to the warrants. As a result, the underwriter has informed us that it intends to exercise its over-allotment option for all of the warrants which are over-allotted, if any, at the time of the initial offering of the shares and the warrants. However, because our common stock is publicly traded, the underwriter may satisfy some or all of the over-allotment of shares of our common stock, if any, by purchasing shares in the open market and will have no obligation to exercise the over-allotment option with respect to our common stock. If the underwriter exercises its over-allotment option with respect to the warrants in full, but does not exercise its over-allotment option with respect to our common stock, then the effective warrant coverage for each share of common stock sold in this offering would be 230% instead of the 200% stated on the cover page of this prospectus.

The number of shares of common stock to be outstanding after the offering is based on 2,207,458 shares of common stock outstanding as of September 30, 2022, and excludes, as of that date, the following:

- 520,962 shares issuable upon the exercise of the Prior Warrants, with a weighted-average exercise price of $3.75 per share, assuming a combined public offering price of $2.37 per share and accompanying warrants (the last reported sale price of our common stock on Nasdaq on November 14, 2022);
- 500,000 shares issuable upon the exercise of the Public Warrants, with a weighted-average exercise price of $230.00 per share;
- 445,063 shares issuable upon the exercise of the LACQ Warrants, with a weighted-average exercise price of $228.31 per share;
- 55,306 shares issuable upon the exercise of the GEM Warrants, with a weighted-average exercise price of $2.37 per share, assuming a combined public offering price of $2.37 per share and accompanying warrants (the last reported sale price of our common stock on Nasdaq on November 14, 2022);
- 10,548,522 shares issuable upon the exercise of Series A warrants and Series B warrants in this offering (assuming a combined public offering price of $2.37 per share and accompanying warrants) (the last reported sale price of our common stock on Nasdaq on November 14, 2022);
- 2,594,092 shares issuable upon conversion of the 2022 Notes (assuming a combined public offering price of $2.37 per share and accompanying warrants) (the last reported sale price of our common stock on Nasdaq on November 14, 2022);
- 326,741 shares issuable upon exercise of stock options outstanding under our 2021 Omnibus Incentive Plan;
- 16,500 shares issuable upon vesting of restricted stock units, or RSU's, outstanding under our 2021 Omnibus Incentive Plan; and
- 44,095 shares reserved for future issuance under our 2021 Omnibus Incentive Plan.

The information discussed above is illustrative only and will adjust based on the actual public offering price and other terms of this offering determined at pricing. Except as indicated otherwise, the discussion and table above assume (i) no sale of pre-funded warrants, which, if sold, would reduce the number of shares of common stock that we are offering on a one-for-one basis, (ii) no exercise of the underwriter's option to purchase additional securities and (iii) no exercise of the warrants being sold in this offering.

MARKET PRICE, TICKER SYMBOL AND DIVIDEND INFORMATION

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 November 14, 2022, was $2.37 and $0.0334, respectively.

Holders

As of November 14, 2022, there were approximately 154 holders of record of our common stock.

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

Dividend Policy

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.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2021 with respect to securities that may be issued under our equity compensation plans:

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the First Column)
Equity compensation plans approved by security holders	222,191	$ 48.06	200,012
Equity compensation plans not approved by security holders	-	-	-
Total	222,191	$ 48.06	200,012

BUSINESS

References in this section to "we," "our," "us," the "Company" or "Ensysce" generally refer to Ensysce and its consolidated subsidiaries.

Business Overview

We are a clinical stage pharmaceutical company seeking to develop innovative solutions for severe pain relief while reducing the potential for opioid misuse, abuse, and overdose.

We are currently developing product candidates designed to improve the safety of prescription drugs. Our primary focus has been on opioid pain products and opioid use disorder products. Prescription opioid abuse presents 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 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 intranasally 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, and, 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 track; (2) rearrangement chemistry to achieve pharmacokinetic release of active drug products; and (3) preclinical and clinical data that set forth the metabolic and chemical activation profile for each of our clinical candidates.

Utilizing this approach, we filed an Investigational New Drug application, or IND (116794), and commenced a Phase 1 clinical trial for PF614, which was completed in February 2018. The clinical data from the Phase 1 trial demonstrated that oxycodone released from PF614 as chemically-designed, and that it was absorbed following oral administration of the TAAP PF614, resulting in blood levels that matched the same release profile as the extended release oxycodone product, OxyContin OP. A second multi-ascending dose study with a bioequivalent arm was completed in July 2022 and a nasal human abuse potential (HAP) study was recently completed with data expected in November 2022. A second oral HAP study has been initiated in September 2022 and data is expected in early 2023.

The MPAR™ technology is designed to limit the bioavailability of active opioid following co-ingestion of multiple doses, whether inadvertent or intentional, through a combination of a TAAP prodrug with nafamostat. Nafamostat is a small molecule that clinical studies have shown to have a steep dose response curve and to be a highly potent trypsin inhibitor. When combined with our TAAP prodrugs, our MPAR technology is designed not to affect metabolism and the release of the active pharmaceutical ingredient. However, if the MPAR combination product is taken in larger quantities than intended, the excess nafamostat is designed to inhibit trypsin, thereby preventing metabolic activation and averting a drug overdose. We believe the potential benefits to society of an opioid that resists both oral and parenteral abuse are considerable. A Phase 1 study to explore the combination of PF614 and nafamostat, PF614-MPAR-101 was initiated in December of 2021, and early data from the study reported in May 2022 demonstrated the combination product showed overdose protection, with a reduction in the release of oxycodone over that of PF614 delivered alone.

Our pipeline has been developed over the course of 15 years of research and investment and 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.

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, on 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.

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 multi-ascending dose study (MAD) 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 (BE) of PF614 versus OxyContin. Final data from this trial was reported in July 2022. The MAD study demonstrated both the safety of PF614 showing it was well tolerated at doses up to 200 mg, which was comparable to 80 mg of OxyContin both delivered twice daily. The BE study arm followed the successful completion of the multi-ascending twice-daily dosing study of PF614 and compared the release of oxycodone from PF614 versus OxyContin® administered to subjects in both fasted and fed states. It was concluded that 100 mg PF614 was bioequivalent to 40 mg OxyContin under both fasted and fed conditions. This data is critical to understand future prescribing criteria for PF614 as an agent bioequivalent to OxyContin and therefore may be developed through the 505(b)(2) regulatory path as defined by the FDA. The intranasal (IN) and oral human abuse potential of PF614 was assessed in two different studies. In study 1 PF614-103, we evaluated the abuse potential of PF614 100 mg relative to crushed oxycodone immediate-release (IR) tablets 40 mg (equivalent opioid doses) and placebo following intranasal administration. In study 2, PF614-104 which is ongoing, we are evaluating the oral abuse potential of intact PF614 at 3 different dose levels 50, 100 and 200 mg to IR oxycodone 40 mg and placebo. The purpose of this study is to assess the pharmacokinetics (PK) and human abuse potential of oral PF614 and data is expected is 2023. 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 on April 27, 2021 following the release of a Full Clinical Hold from January 8, 2021. We addressed deficiencies from the initial IND submission, amended the protocol and submitted a response to the clinical hold letter on March 29, 2021. We initiated a Phase 1 clinical trial, PF614-MPAR-101, to evaluate safety and PK in healthy subjects in December 2021. Initial data from this trial was reported in May of 2022. The PF614-MPAR-101 overdose protection study examined PF614 administered orally alone or in combination with the trypsin inhibitor nafamostat (MPAR) to healthy volunteers. The initial data demonstrated the overdose protection of our MPAR combination product, with reduced release of oxycodone from PF614 in a simulated overdose situation. It also demonstrated the PF614 in the systemic circulation (simulated injection) did not convert to oxycodone. The study is continuing to enroll subject in this study and final data will be available in mid-2023

MPAR is being tested clinically in partnership with Quotient Sciences, using its integrated Translational Pharmaceutics® platform to search for a PF614-MPAR formulation that allows conversion into oxycodone within the prescribed dose range but reduces conversion to oxycodone at higher than prescribed dose levels in an overdose scenario.

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 drug product of nafamostat, 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.

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. An NIH study, updated September 2018, 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. High impact chronic pain affects over 10 million Americans and is characterized by extended periods of suffering which impair life quality to a severe degree. Prescription opioids drugs, such as morphine, hydromorphone, hydrocodone, and oxycodone, have a long history of use for the management of severe and chronic pain. Prescriptions for opioid medications in 2021 totaled 153 million, with $4.2 billion in market size in the United States.

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 are based on the indications, acute and chronic pain, that we intend to explore for our 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 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 91 people died each day from opioid-related overdoses. Currently, that number has risen to approximately 188 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, 2.1 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 insufflated 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, benzodiazepines or other drugs to enhance 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 Aderall are manufactured in pill form and are intended for oral ingestion. As of Q4 2022, seventy-five percent of Adderall prescriptions are prescribed to the 10.5 million adults, age 22 or older, 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 prescribed for 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 other coronavirus outbreaks, sales of Tamiflu® were $950 million in the US and $2.426 billion cumulative sales worldwide (2016-2020). Sales of Paxlovid from Pfizer for COVID-19 totaled $8.85 Billion in Q2, 2022 and is reported to be set to generate $23 Billion in 2022, an indication of the continuing unmet need for treatments around the world.

The World Health Organization estimates influenza epidemics result in approximately three to five million cases of severe illness and 290,000 to 650,000 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). Our TAAP prodrugs delivery system demonstrates a number of 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. First, the abuse-resistance provided by TAAP 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.

Besides our clinical candidates, we have a product portfolio of other TAAP and MPAR™ opioids and amphetamines that could potentially be developed to build on this pipeline.

Clinical agents

PF614

PF614 is a chemically modified, extended-release 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 a number of ways. First, 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.

PF614-102 Phase 1b Clinical Trial

Phase 1b study, A PHASE 1B, RANDOMIZED, 2-PART SINGLE-CENTER STUDY TO EVALUATE THE PHARMACOKINETICS AND SAFETY OF MULTIPLE-ASCENDING ORAL DOSES OF PF614 AND THE FOOD EFFECT AND BIOAVAILABILITY/BIOEQUIVALENCE OF SINGLE ORAL DOSES OF PF614 RELATIVE TO OXYCONTIN IN HEALTHY ADULT SUBJECTS, was conducted by ICON (formerly PRA Health Sciences) with Dr. M Johnston as Principal investigator. This was a 2-part study comprised of a MAD study (Part A) and a comparative bioavailability/bioequivalence and food effect study (Part B) in healthy subjects. Part A treated a total of 24 subjects and utilized a randomized, open-label, MAD design with up to 3 separate dose groups of 8 subjects per group. Within each dose group, subjects were randomized to receive either PF614 (n=6) or OxyContin (n=2). Subjects received repeated BID doses, planned to be administered every 12 hours (q12h) over a 5-day period, for a total of 9 doses. PF614 doses were 50 mg, 100 mg, and 200 mg, which were expected to be approximately equivalent to the 20 mg, 40 mg, and 80 mg OxyContin doses, for Dose Groups 1, 2, and 3, respectively. Serial PK sampling was performed for the first day/first dose (Day 1) and for the last day/last dose (Day 5). Only trough PK samples were taken within 30 minutes prior to the morning dose on Days 2, 3, and 4. Safety assessments, including regular assessments of adverse events (AEs), vital signs (pulse rate, blood pressure, respiratory rate, and oxygen saturation [SpO_2]), clinical laboratory tests, 12-lead electrocardiograms (ECGs), and cardiac telemetry were monitored throughout the study. Subjects were monitored for hypotension, hypopnea, apnea, and oxygen desaturation.

Part B treated a total of 60 subjects and utilized an open-label, single-dose, randomized, 4-way crossover design. Subjects were randomized to receive each of the following single oral doses of study drugs in a Williams design crossover manner (1 at each treatment period):

- Treatment A: 100 mg PF614, administered under fasted conditions (hereafter referred to as 100 mg PF614, fasted)
- Treatment B: 100 mg PF614, administered under fed conditions (high-fat breakfast) (hereafter referred to as 100 mg PF614, fed)
- Treatment C: 40 mg OxyContin, administered under fasted conditions (hereafter referred to as 40 mg OxyContin, fasted)
- Treatment D: 40 mg OxyContin, administered under fed conditions (high-fat breakfast) (hereafter referred to as 40 mg OxyContin, fed)

Each treatment was separated by a washout interval of 5 days. Serial PK sampling was performed after each study drug administration up to 120 hours postdose. Safety including regular assessments of AEs, vital signs (pulse rate, blood pressure, respiratory rate, and SpO_2), clinical laboratory tests, and 12-lead ECGs were monitored. Subjects were monitored for hypotension, hypopnea, apnea, and oxygen desaturation.

Pharmacokinetics

Part A: The shape of the plasma concentration versus time curve of oxycodone was similar following administration of PF614 and OxyContin (oxycodone extended release). Oxycodone plasma exposure (T_{max}, $C_{max,ss}$ and AUC_{tau}) were assessed and PF614 showed similar trends as OxyContin following administration of multiple oral BID doses. Due to the small sample number for OxyContin some PK parameters could not be calculated. Trough concentrations of oxycodone were generally similar from Day 2 through Day 4, suggesting that subjects achieved steady state after repeated oral BID dosing of PF614 and OxyContin at all dose levels.

Part B: A total of 57 subject were included in the PK analyses. The data for C_{max}, AUC_{0-t}, and AUC_{0-inf} of oxycodone post 100 mg PF614 versus 40 mg OxyContin dosing under fasted and fed conditions were completely contained within the standard bioequivalence limits of 80% to 125%. Therefore, it was concluded that 100 mg PF614 was

bioequivalent to 40 mg OxyContin under both fasted and fed conditions.

Safety

PF614 was generally safe and well-tolerated following oral administration of 50 mg, 100 mg, or 200 mg PF614 BID for 5 days. There was no apparent difference in the safety profile of single oral doses of 100 mg PF614 when administered in the fasted or fed state or between PF614 and OxyContin when administered in the fasted and fed state. PF614 was generally safe and well-tolerated following single and multiple oral doses under naltrexone blockade.

PF614-103 Intranasal Human Abuse Potential Clinical Trial

PF614-103 was a randomized, double-blind, placebo- and active-controlled, 3-way crossover study to evaluate the abuse potential and pharmacokinetics of intranasally administered PF614, relative to crushed oxycodone IR tablets and placebo, in non-dependent recreational opioid users conducted by Lotus Clinical Trials LLC through Ohio Clinical Trials, Inc with Principal investigator, Dr. G. Apseloff.

The study consisted of 4 phases: Screening, Qualification, Treatment, and Follow-up. Subjects were randomized to receive PF614 100mg or crushed oxycodone 40 mg intranasally. The primary objective of the study was to evaluate the abuse potential of PF614 relative to crushed oxycodone immediate-release (IR) tablets and placebo following intranasal administration in non-dependent recreational opioid users (n=26), with the primary pharmacodynamic endpoint being the maximum effect (E_{max}) for Drug Liking ("*at this moment*") measured up to 24 hours after dosing using a visual analogue scale (VAS). The secondary objectives of the study were to evaluate the pharmacokinetic profile of PF614 relative to crushed oxycodone IR tablets following intranasal administration, to evaluate the safety of PF614 following intranasal administration.

In the study, PF614 powder produced a statistically significant lower peak "drug liking" (Emax) when compared with intranasal crushed IR oxycodone (p = 0.0133) using the full modified completer population in a 3-period crossover of PF614 vs. crushed oxycodone and placebo. Furthermore, in a first period analysis of initial impressions of each drug, a statistically significant difference was noted between PF614 (n=8) and crushed IR oxycodone (n=10) (p = 0.0175), even with this smaller cohort of subjects.

Statistically significant differences in peak effects (Emax) between PF614 and crushed IR oxycodone intranasal were also demonstrated for the secondary endpoint of "take drug again," also using a first period analysis (p < 0.0001).

The intranasal HAP study was designed to test if known recreational drug users "*liked*" the product and is critical for labeling claims for new drugs in this class. The primary measure in this study, "*drug liking*," is recommended by the FDA in their Guidance on "Assessment of Abuse Potential of Drugs." This measure is known to correlate with a drug's potential for abuse. The results demonstrated that inhaled powdered PF614 had significantly lower drug liking than inhaled crushed IR oxycodone.

Next Steps

In 2022 we initiated two human abuse potential studies of PF614 to understand the tendency for drug abusers to like the effects achieved from taking PF614 either orally or intranasally as compared to that of a comparator product such as crushed oxycodone. The data from these studies will be used to support our application for 'Abuse Deterrent' labeling for PF614. The data from the intranasal study was reported on October 31, 2022 and the data from the oral study is expected to be available in early 2023. We intend to explore pain indications to evaluate PF614 for efficacy and safety which we are seeking to initiate in 2023. 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 "*—Federal Grants*" for additional information.

In November 2022, we received written guidance from the FDA that an acute pain indication may be appropriate for PF614. The FDA guidance, while not binding, states that our proposed clinical development approach of conducting at least two adequate and well-controlled clinical trials in two different pain models comparing PF614 to a placebo and to another immediate release (IR) opioid, such as IR oxycodone, appears reasonable to support a new drug application for PF614 for an acute pain indication. The FDA guidance also provides additional guidance with respect to the non-clinical studies and clinical trials planned by us. The clinical development pathway of PF614 for an acute pain indication may reduce the development timeline and be more cost-effective than initially pursuing a chronic pain indication for PF614.

<u>PF614-MPAR™</u>

We initiated a Phase 1 study that is evaluating PF614-MPAR™ in study 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:" We are clinically testing MPAR in partnership with Quotient Sciences, using its integrated Translational Pharmaceutics® platform to search for a PF614-MPAR formulation that allows conversion into oxycodone within the prescribed dose range but reduces conversion to oxycodone at higher than prescribed dose levels in an overdose scenario.

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. Initial data was reported in May 2022 that demonstrated nafamostat administer in combination with PF614 in a simulated overdose situation reduced the release of oxycodone from PF614 as designed. The study will continue in 2023 to test the overdose protection of the selected formulation by administering an escalating number of dose units to a group of healthy subjects. Data is expected in the second half of 2023.

<u>NAFAMOSTAT</u>

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 the most 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 will 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 planning to evaluate nafamostat in a Phase 2 clinical trial in COVID-19 subjects when delivered as an oral drug product. Nafamostat 200 mg capsules have been manufactured and are on stability evaluation.

Competition

The life sciences 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. Most of these existing and potential competitors have significantly greater financial 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 safety and tolerability, the ability of our product candidates to limit human abuse potential, bioavailability and therapeutic efficacy of our product candidates, and convenience of dosing and distribution. PF614 will also face competition from commercially available generic and branded extended-release and long-acting opioid drugs other than oxycodone, including, but not limited to, fentanyl, hydromorphone, oxymorphone, and methadone, as well as opioids that are currently in clinical development.

We believe that obtaining an abuse-deterrent label through the FDA for our prodrugs would provide us with a significant competitive advantage. 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. However, obtaining an abuse-deterrent label involves a lengthy and complicated process with no certainty of success. 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.

A number of other companies including, but not limited to, Pfizer Inc., Daiichi Sankyo, Endo Health Solutions, Nektar Therapeutics, 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 similar to 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.

In August 2020, EBIR entered into a Technology Transfer Agreement with Mucokinetica to acquire its intellectual property and all assets associated with the inhaled nafamostat program. Specifically, EBIR acquired Patent EP2124926B1 and all data and assets associated with the development and expansion of the inhaled nafamostat program. These assets included COVID-19 and cystic fibrosis drug targets in development.

In consideration for this intellectual property, Mucokinetica received a 1% equity ownership in EBIR, and its founders, Roderick Hall and Peter Cole, entered into Consulting Agreements with EBIR. The Consulting Agreements were subsequently terminated by Messrs. Hall and Cole.

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 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 natural or projected expiry dates is presented below.

	Countries of Filings	Natural or 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
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	PCT	2041
Oral formulations of Nafamostat	U.S.	2042
Methods of Treating Respiratory Diseases with mucostasis	Germany, France, Italy, United Kingdom	2038
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	PCT	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 we 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.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States 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 and the total patent term including the restoration period must not exceed fourteen years following FDA approval. 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, Europe, 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 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, Europe, 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 pending provisional application directed to 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, Europe, 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 expire in 2032. 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 one pending provisional 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 Ltd. 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 2038, subject to any applicable patent term extension that might be available in Europe Union or United Kingdom. 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, but intends to file pending applications upon development of a suitable inhalation formulation of nafamostat. We believe that one patent covering nafamostat will be eligible for up to five years of patent term extension in the United States and Europe and intend to pursue such extension. 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 pending applications in the United States and numerous European foreign jurisdictions 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 pending Patent Cooperation Treaty, or PCT, application 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, which we intend to pursue in the United States and in certain significant commercial markets. We have not obtained assignments from all of the inventors of this PCT application 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

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. Our drug substance and drug products are manufactured for us by contract manufacturing organizations, or CMOs, to our specifications. Any manufacturing problem or the loss of a CMO could be disruptive to our operations and result in lost sales.

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 CMOs 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 CMO 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.

Purisys

Purisys LLC manufactures PF614 and other clinical trial materials under cGMP conditions and provides stability studies with respect to our PF614 clinical trials. We do not currently have a binding written agreement with Purisys. In the event that Purisys is unable to perform the services promised under future agreements, we may be subject to unforeseen costs and delays with respect to our clinical trials and may be unable to replace the Purisys arrangements 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.

Recro

Recro manufactures PF614 and other clinical trial drug products under cGMP conditions and provides stability studies with respect to our PF614 clinical trials. Recro (now Societal CDMO) has completed the manufacture of PF614 50 and 100 mg capsules that have been used in clinical studies PF614-102, PF614-103 and PF614-104.We expect to enter into additional related agreements with Societal CDMO as we manufacture future batches of PF614. In the event that Societal is unable to perform the services anticipated under future agreements, we may be subject to unforeseen costs and delays with respect to our clinical trials. 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 have received funding under federal grant award programs through governmental agencies, such as the NIH and NIDA. For fiscal year 2021, we received an aggregate of approximately $3.5 million in federal grant funds, 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™ technology. For the nine months ended September 30, 2022, we received federal grants totaling $1.1 million, $0.7 million from NIH related to the Phase 1 clinical trial for PF614 MPAR™ and $0.4 million from NIDA for preclinical development of our opioid use disorder-MPAR™ technology. Current remaining funding under the two approved grants totals $5.8 million, covering the period through August 31, 2023. We may apply for additional grant funding from these or similar governmental agencies in the future.

GEM Facility

Pursuant to the GEM Agreement, we are entitled to draw down up to $60 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 equity line 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. We are entitled to request a draw down of up to $10 million in the first month following the closing of the Merger subject to Draw Down Limit and other conditions provided in the GEM Agreement.

Further, 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, was paid in July 2022 and the commitment fee for the second tranche, which is equal to the remaining 33% of the commitment fee, or $400,000, becomes payable in January 2023.

Additionally, we issued a warrant with a 36-month term at the closing of the Merger granting GYBL the right to purchase 55,306 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, prior to the offering that is the subject of this prospectus, $3.28. Any failure by us to timely transfer the shares under the warrant pursuant to GYBL's exercise will entitle GYBL 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 and reverse stock splits. The strike price is subject to adjustment for issuances of additional common shares at a price per share less than the strike price and may reset because of the offering described in this prospectus.

The GEM Agreement contains certain negative covenants restricting us from securing an equity 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. To date, we have not raised any capital pursuant to 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 Federal Food, Drug, and Cosmetic Act (the "*FDC Act*"), the Controlled Substances Act ("*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 for Fiscal Year 2022. Under an approved NDA, the applicant is also subject to an annual program fee, currently exceeding $330,000. 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 such 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.

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.

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 designation, 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, including, 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, who 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.

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 2023. 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.

Employees

As of November 14, 2022 we had seven full-time employees and five 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.

Legal Proceedings

As of the date hereof, we are not a party to any material legal proceeding.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provide information which our management believes is relevant to an assessment and understanding of our consolidated results of

operations and financial condition. You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and notes thereto included elsewhere in this prospectus. In addition to historical financial information, this discussion contains forward-looking statements based upon our current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Item 1A. Risk Factors."

Overview

Since inception in 2003, we have devoted substantially all 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 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 have incurred significant operating losses since inception. As of September 30, 2022, we had an accumulated deficit of $105.4 million. 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 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 continue existing and initiate new clinical trials for our product candidates;
- advance the development of our 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 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;
- 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.

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.

Recent Developments

Reverse Stock Split

On October 27, 2022, we filed an amendment to our Third Amended and Restated Certificate of Incorporation with the State of Delaware for a one-for-twenty reverse split of our common stock (the "*Reverse Split*"), which became effective October 28, 2022. All share and per share information has been restated retroactively, giving effect to the Reverse Split for all periods presented. There was no change to reported net loss in any period presented.

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 National Institutes of Health ("*NIH*") through the National Institute on Drug Abuse ("*NIDA*"). In September 2018, we were awarded a research and development grant related to the development of our MPAR™ overdose prevention technology (the "*MPAR Grant*"). In September 2019, we were awarded a second research and development grant related to the development of our TAAP/MPAR ™ abuse deterrent technology for Opioid Use Disorder ("*OUD*") (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 contract research organizations ("*CROs*") that are primarily engaged in the oversight and conduct of our drug discovery efforts and preclinical studies, clinical trials and contract manufacturing organizations ("*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 development 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 investigational new drug ("*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, 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, 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 continue to incur significant accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses 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)

Change in fair value of 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.

Change in fair value of convertible notes

We elected the fair value option to account for the 2021 Notes and 2022 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 discounted cash flow model and a Monte Carlo analysis to estimate the fair value of the notes, both of which rely on unobservable Level 3 inputs. Changes in the fair value of the notes are recognized through earnings for each reporting period.

Change in fair value of liability classified warrants

The warrants issued with the 2021 Notes and 2022 Notes are 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.

Loss on debt conversions

When conversions on the 2021 Notes and 2022 Notes occur, we calculate the difference between the conversion price and the average of the high and low stock price on the date of conversion. The resulting difference is either a loss if the conversion price was below the average of the high and low stock price on the date of conversion or a gain if the conversion price was above the average of the high and low stock price on the date of conversion.

Interest expense

Interest expense consists of interest accrued on our financed directors and officers insurance as well as imputed interest on the commitment fees related to the share subscription facility.

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 September 30, 2022, 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 2015 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 three months ended September 30, 2022 and 2021:

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		
	2022	2021	Change
Federal grants	$ 279,351	$ 1,200,816	$ (921,465)
Operating expenses:			
Research and development	4,756,096	1,714,635	3,041,461
General and administrative	1,686,580	16,372,976	(14,686,396)
Total operating expenses	6,442,676	18,087,611	(11,644,935)

Loss from operations	(6,163,325)	(16,886,795)	10,723,470
Other income (expense):			
Issuance costs for convertible notes	(1,118,721)	(500,158)	(618,563)
Loss on issuance of convertible notes	(3,609,944)	-	(3,609,944)
Change in fair value of convertible notes	3,491,513	1,071,099	2,420,414
Issuance of liability classified warrants	(3,737,371)	(1,325,804)	(2,411,567)
Change in fair value of liability classified warrants	2,683,340	405,086	2,278,254
Loss on debt conversions	(1,404,877)	-	(1,404,877)
Interest expense	(4,859)	(24,660)	19,801
Other income and expense, net	8,679	61,758	(53,079)
Total other income (expense), net	(3,692,240)	(312,679)	(3,379,561)
Net loss	$ (9,855,565)	$ (17,199,474)	$ 7,343,909
Net loss attributable to noncontrolling interests	(21,492)	(35,948)	14,456
Deemed dividend related to warrants down round provision	63,539	-	63,539
Net loss attributable to common stockholders	$ (9,897,612)	$ (17,163,526)	$ 7,265,914

Federal grant funding

Funding from federal grants for the three months ended September 30, 2022 and 2021 totaled $0.3 million and $1.2 million, respectively, representing a decrease of $0.9 million. Differences are due to the timing of research activities eligible for funding as well as the grant period. We expect funding from federal grants to generally increase in the future due to the timing of preclinical and clinical development activities under the grants.

Research and development expenses

Research and development expenses for the three months ended September 30, 2022 and 2021 were $4.8 million and $1.7 million, respectively, representing an increase of $3.0 million. The increase was primarily the result of increased external research and development costs related to clinical and pre-clinical programs for PF-614 and PF614-MPAR™. We do not currently track expenses on a program-by-program basis. We expect future research and development expenses to approximate current levels.

General and administrative expenses

General and administrative expenses for the three months ended September 30, 2022 and 2021 were $1.7 million and $16.4 million, respectively, representing a decrease of $14.7 million. The decrease was primarily a result of non-cash expenses incurred in the comparable prior period in connection with the valuation of issued warrants. We expect future general and administrative expenses to approximate current levels.

Other income and expense

Issuance costs for convertible notes increased due to both tranches of the 2022 Notes being issued during the period while only one tranche of the 2021 Notes was issued during the similar prior period. The loss on issuance of the convertible notes was due to the current share price at issuance (of the 2022 Notes) exceeding the conversion price. Changes in fair value of convertible notes and liability classified warrants for the 2022 period relate to both the 2021 Notes and 2022 Notes compared to only changes related to the 2021 Notes in the prior period. Loss on debt conversions is driven by the difference between the conversion price of the 2021 Notes and 2022 Notes and the average of the high and low stock price on the date of conversion. There was no corresponding activity in the 2021 period.

Comparison of the nine months ended September 30, 2022 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		
	2022	**2021**	**Change**
Federal grants	$ 1,089,920	$ 1,895,907	$ (805,987)
Operating expenses:			
Research and development	13,393,948	2,502,232	10,891,716
General and administrative	5,717,281	17,257,361	(11,540,080)
Total operating expenses	19,111,229	19,759,593	(648,366)
Loss from operations	(18,021,309)	(17,863,686)	(157,623)
Other income (expense):			
Issuance costs for convertible note	(1,118,721)	(500,158)	(618,563)
Change in fair value of derivative liabilities	-	673,314	(673,314)
Loss on issuance of convertible notes	(3,609,944)	-	(3,609,944)
Change in fair value of convertible notes	6,169,929	1,071,099	5,098,830
Issuance of liability classified warrants	(3,737,371)	(1,325,804)	(2,411,567)
Change in fair value of liability classified warrants	5,626,130	405,086	5,221,044
Loss on debt conversions	(4,000,155)	-	(4,000,155)
Interest expense	(57,662)	(1,282,820)	
Loss on extinguishment of debt	-	(347,566)	347,566
Other income and expense, net	19,494	61,758	(42,264)
Total other income (expense), net	(708,300)	(1,245,091)	536,791
Net loss	$ (18,729,609)	$ (19,108,777)	$ 379,168
Net loss attributable to noncontrolling interests	(47,619)	(61,976)	14,357
Deemed dividend related to warrants down round provision	881,598	-	881,598
Net loss attributable to common stockholders	$ (19,563,588)	$ (19,046,801)	$ (516,787)

Federal grant funding

Funding from federal grants for the nine months ended September 30, 2022 and 2021 totaled $1.1 million and $1.9 million, respectively, representing a decrease of $0.8 million.

Differences are due to the timing of research activities eligible for funding as well as the grant period. We expect funding from federal grants to generally increase in the future due to the timing of preclinical and clinical development activities under the grants.

Research and development expenses

Research and development expenses for the nine months ended September 30, 2022 and 2021 were $13.4 million and $2.5 million, respectively, representing an increase of $10.9 million. The increase was primarily the result of increased external research and development costs related to clinical programs for PF614 and preclinical programs for PF614-MPAR™. We do not currently track expenses on a program-by-program basis. We expect future research and development expenses to approximate current levels.

General and administrative expenses

General and administrative expenses for the nine months ended September 30, 2022 and 2021 were $5.7 million and $17.3 million, respectively, representing a decrease of $11.5 million. The decrease was primarily a result of non-cash expenses incurred in the comparable prior period in connection with the valuation of issued warrants. We expect future general and administrative expenses to approximate current levels.

Other income and expense

Changes in the fair value of derivative liabilities during the nine months ended September 30, 2021 resulted from the decreased likelihood of realization of the embedded derivative instrument in convertible notes payable, resulting in a gain of $0.7 million during the nine months ended September 30, 2021. All outstanding liabilities were settled in connection with the conversion of outstanding note payables on June 30, 2021.

Issuance costs for convertible notes increased due to both tranches of the 2022 Notes being issued during the period while only one tranche of the 2021 Notes was issued during the similar prior period. The loss on issuance of the convertible notes was due to the current share price at issuance (of the 2022 Notes) exceeding the conversion price. Changes in fair value of convertible notes and liability classified warrants for the 2022 period relate to both the 2021 Notes and 2022 Notes compared to only changes related to the 2021 Notes in the prior period. Loss on debt conversions is driven by the difference between the conversion price of the 2021 Notes and 2022 Notes and the average of the high and low stock price on the date of conversion. There was no corresponding activity in the 2021 period.

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 55,306 warrants issued with an exercise price of $200.20 per share in July 2021, based on the $289.80 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 September 30, 2022, we had $4.5 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 September 30, 2022, we had an accumulated deficit of $105.4 million. Based on our cash on hand at September 30, 2022 and assuming that we receive net proceeds of approximately $11.3 million from this offering, we anticipate having sufficient cash to fund our planned operations to mid-2023.

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 likely 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 continue to fund our operations through public or private equity or debt financings or other sources which may include potential collaboration agreements. We cannot make assurances that anticipated additional financing will be available to us on favorable terms, if at all.

Current remaining funding under two approved federal research grants totals $5.8 million, covering the period through August 31, 2023. 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 Investor Notes are outstanding.

Upon the public listing of the Company's shares following 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, was discharged with 46,062 shares of common stock transferred from related parties in July 2022. The commitment fee for the second tranche, which is equal to the remaining 33% of the commitment fee, or $400,000, becomes payable in January 2023.

Additionally, we issued a warrant with a 36-month term at the closing of the Merger granting GEM Global the right to purchase 55,306 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, prior to the offering described in this prospectus, $3.28. 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 a 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.

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 a securities purchase agreement for an aggregate financing of $15.0 million with institutional investors. The Company issued to the investors (i) 2021 Notes in the aggregate principal amount of $15.9 million for an aggregate purchase price of $15.0 million and (ii) warrants to purchase 54,174 shares of the Company's common stock in the aggregate. The 2021 Notes have been repaid. The exercise price of the warrants is $15.60 per share prior to the offering described in this prospectus.

On June 30, 2022, we entered a Securities Purchase Agreement for an aggregate financing of $8.0 million with institutional investors. The Company issued to the investors (i) 2022 Notes in the aggregate principal amount of $8.48 million for an aggregate purchase price of $8.0 million and (ii) warrants to purchase 466,788 shares of the Company's

common stock in the aggregate. Prior to the offering described in this prospectus, the conversion price for the 2022 Notes was $10.90 per share, and the exercise price of the warrants was $14.17 per share. The first funding of $4.0 million occurred on July 1, 2022 and the second funding of $4.0 million occurred on August 9, 2022.

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.

Cash flows

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

	Nine Months Ended September 30,	
	2022	**2021**
Net cash used in operating activities	$ (14,591,819)	$ (4,474,364)
Net cash provided by investing activities	4,500	-
Net cash provided by financing activities	6,825,664	11,125,822
Net increase (decrease) in cash and cash equivalents	$ (7,761,655)	$ 6,651,458

Operating activities

During the nine months ended September 30, 2022 and 2021, we used cash in operating activities of $14.6 million and $4.5 million, respectively. The increase primarily resulted from the clinical advancement of our product candidates, the timing of vendor invoicing and payments, and increased costs related to operating as a public company.

Investing activities

During the nine months ended September 30, 2022, net cash provided by investing activities was $4,500 from the sale of certain property and equipment.

Financing activities

During the nine months ended September 30, 2022, net cash provided by financing activities was $6.8 million, primarily consisting of proceeds from the issuance of the 2022 Notes, net repayment of financed insurance premiums and cash payment of convertible notes. During the nine months ended September 30, 2021, net cash provided by financing activities was $11.1 million, primarily consisting of proceeds from Business Combination and convertible note financing.

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 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 Business Combination, 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, 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.

Going concern

We have generated limited revenues and have incurred significant operating losses since our inception and, as of September 30, 2022, had an accumulated deficit of $105.4 million. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future.

Following the completion of the Business Combination and public listing of our common stock on Nasdaq, we had access to up to $60.0 million from a share subscription facility under the GEM Agreement. The 2022 Notes limit our ability to execute certain debt and equity financings, including under the GEM Agreement, while the 2022 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 prospectus, which raises substantial doubt about the Company's ability to continue as a going concern.

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 unaudited interim consolidated financial statements appearing elsewhere in this prospectus, 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 performance-based vesting conditions. Compensation expense related to awards to employees and non-employees with performance-based vesting conditions is recognized based on the grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. We estimate the probability that certain performance criteria will be met and do not recognize compensation expense until it is probable that the performance-based vesting condition will be achieved.

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. The Company determined that the 2022 Notes should be recorded at estimated fair value on its issuance date and adjusted to its estimated fair value as of each reporting date. We use a Monte Carlo simulation model to estimate the fair value of the 2021 Notes and 2022 Notes, which relies on unobservable Level 3 inputs. Changes in the fair value of the notes are recognized through earnings for each reporting period.

Off-balance sheet arrangements

We do not have during the periods presented, and do not 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 consolidated financial position and results of operations is disclosed in Note 3 to our consolidated financial statements included elsewhere in this prospectus.

Emerging growth company and smaller reporting company status

We are an "*emerging growth company*," as defined in the Jumpstart Our Business Startups Act (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 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.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

Other than the agreements and arrangements described under the section entitled "*Executive & Director Compensation*" in this Registration Statement and the transactions described below, since January 1, 2019, there has not been and there is not currently proposed, any transaction or series of similar transactions to which (i) we were, or will be, a participant; (ii) the amount involved exceeded, or will exceed, $120,000 or 1% of the average of our total assets at December 31, 2020 and 2021; and (iii) in which any director, executive officer, holder of 5% or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of the foregoing persons, had, or will have, a direct or indirect material interest.

EBIR

We own 79.2% of the issued and outstanding shares of EBIR, a clinical stage pharmaceutical company that is developing a compound utilized in our overdose protection program for the treatment of COVID-19. The other 20.8% is owned by two affiliates of Ensysce and Mucokinetica. Specifically, our Chief Executive Officer and Director, Dr. Lynn Kirkpatrick, owns 9.9%, our Chief Business Officer, Richard Wright, owns 9.9% and Mucokinetica owns 1.0%. Dr. Kirkpatrick is also Chief Executive Officer of EBIR. There is no revenue sharing agreement between us and EBIR.

Promissory Notes

EBIR held a promissory note issued by us in the principal amount of $200,000 that was repaid in July 2022. The note accrues simple interest at a rate of 12% until the note is paid in full. The principal amount of the note, together with accrued and unpaid interest, was payable in full on the earlier of (i) July 31, 2022 or (ii) receipt by us of an aggregate of least $5 million in gross proceeds from the sale of our securities. The note was secured by 2,000 shares of EBIR's common stock (representing 1.98% of the outstanding common stock of EBIR). The note contained customary covenants to protect EBIR's collateral thereunder.

Dr. Kirkpatrick and Andrew Benton, two of our directors, previously held promissory notes issued by us in the principal amount of $50,000. These notes were repaid in July 2021.

On March 16, 2021, Dr. Kirkpatrick loaned $100,000 to us and Bob Gower, our Chairman, loaned $200,000 to us and each of them was issued a promissory note. These notes were repaid in July 2021.

Convertible Notes

Bob Gower, our Chairman, previously held unsecured 10% Convertible Promissory Notes in the aggregate amount of $2,500,000 issued on the following dates for the following amounts:

- May 4, 2018 in the amount of $600,000;
- September 14, 2018 in the amount of $1,000,000;
- December 31, 2018 in the amount of $500,000;
- October 17, 2019 in the amount of $100,000;
- January 23, 2020 in the amount of $100,000;
- March 9, 2020 in the amount of $100,000; and
- April 15, 2020 in the amount of $100,000 (together, the "*Gower Notes*").

The Gower Notes were converted into shares of our common stock at a conversion price of $0.23 upon the consummation of the Business Combination.

LACQ Related Party Transactions

Private Warrants

On January 31, 2021, in connection with entering into the Merger Agreement, LACQ entered into a warrant surrender agreement, by and among LACQ and its sponsors and strategic investor, HG Vora Capital Management LLC ("*HG Vora*"), pursuant to which each of its sponsors and HG Vora agreed to irrevocably forfeit and surrender 12,500 warrants (the "*Private Placement Warrants*") immediately prior to, and contingent upon, the closing of the Business Combination.

On June 7, 2021, the holders of the Private Placement Warrants and private warrants held by affiliates of the sponsors, HG Vora and certain members of LACQ's management exchanged their warrants for warrants on the same terms as the Private Placement Warrants and private warrants, except that they were not issued under the warrant agreement governing the private warrants and were non-transferable except to permitted transferees.

Contingent Forward Purchase Contract with HG Vora

On December 27, 2019, in connection with a proposed business combination with GTWY Holdings Limited, an amendment to a contingent forward purchase contract was effected to provide that the contingent forward purchase contract would terminate as of, and contingent upon, the closing of the transaction with GTWY Holdings Limited such that HG Vora would purchase 150,000 units of GTWY Holdings Limited's equity securities for a purchase price of $200.00 per unit. In addition, HG Vora waived its rights under the contingent forward purchase contract to purchase private placement units in connection with the Business Combination.

Administrative Services Agreement

On June 30, 2020, Hydra Management, LLC agreed to stop charging a monthly administrative fee and forgave the $71,000 outstanding balance due under the administrative services agreement between LACQ and Hydra Management, LLC.

Expense Advance Agreement

On January 15, 2020, LACQ issued promissory notes pursuant to drawdowns under an expense advancement agreement among LACQ, its sponsors and HG Vora in the aggregate amount of $1,000,000, which the holders elected to convert on June 25, 2020, in accordance with the terms thereunder, into warrants at a price of $20.00 per warrant. LACQ entered into amendments to its expense advancement agreement with its Sponsors and HG Vora dated June 29, 2020, October 26, 2020, November 30, 2020 and February 23, 2021 which, in the aggregate increased the total amount of advances available to it under the expense advancement agreement to $1,460,000. LACQ issued unsecured promissory notes to such parties on October 26, 2020 and October 27, 2020, which were amended and restated on November 30, 2020 and February 24, 2021. Such promissory notes covered outstanding loans in an amount of $460,000 at March 10, 2021. The promissory notes did not bear any interest. The sponsors and HG Vora converted the outstanding loaned amounts under the promissory notes to warrants at a price of $20.00 per warrant prior to consummation of the Business Combination and LACQ issued to the sponsors and HG Vora warrants to purchase 25,500 shares of common stock.

Registration Rights

The holders of the founder shares, Private Placement Warrants and private warrants issued upon conversion of working capital loans (and any shares of common stock issuable upon the exercise of the Private Placement Warrants and warrants that may be issued upon conversion of working capital loans) are entitled to registration rights pursuant to a registration rights agreement entered into by LACQ on the closing of its initial public offering, which requires us to register such securities for resale. In furtherance of this obligation, certain of these securities were previously included in a Registration Statement that was declared effective by the SEC. Each of the sponsors (collectively with their respective affiliates) and HG Vora is entitled to make up to two demands, excluding short form demands, that we register such securities. In addition, the holders have certain "*piggy-back*" registration rights with respect to registration statements filed subsequent to the completion of the Business Combination and rights to require us to register for resale such securities pursuant to Rule 415 under the Securities Act. A registration statement/prospectus covering 250,000 of those founder shares was previously declared effective by the SEC. We will bear the expenses incurred in connection with the filing of any such registration statements.

RELATED PARTY TRANSACTION POLICY

Upon consummation of the Merger, the Board adopted a written related person transaction policy that sets forth the following policies and procedures for the review and approval or ratification of related person transactions.

An "*Immediate Family Member*" means a child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, or any person sharing the household (other than a tenant or employee).

A "*Related Party*" means any (a) person who is or was (since the beginning of the last fiscal year for which we have filed a Form 10-K and proxy statement, even if they do not presently serve in that role) an executive officer, director or nominee for election as a director of the Company, (b) greater than 5% beneficial owner of the Company's outstanding common stock, or (c) Immediate Family Member of any of the foregoing.

A "*Related Person Transaction*" is any Transaction involving the Company in which a Related Party has or will have a direct or indirect material interest, as determined by the Audit Committee.

A "*Transaction*" means any financial transaction, arrangement or relationship or any series of similar transactions, arrangements or relationships, including indebtedness and guarantees of indebtedness and transactions involving employment and similar relationships.

Under the policy, the following types of Transactions are deemed not to create or involve a material interest on the part of the Related Party, nor will they require approval or ratification, under the policy:

- Transactions involving the purchase or sale of products or services in the ordinary course of business, not exceeding $50,000 or, if the Company is a "*smaller reporting company*" as defined under the Securities Act, if less, one percent of the average of the Company's total assets as of December 31st for the last two completed fiscal years.
- Transactions in which the Related Party's interest derives solely from his or her service as a director of another corporation or organization that is a party to the Transaction.
- Transactions in which the Related Party's interest derives solely from his or her ownership of less than 5% of the equity interest in another person (other than a general partnership interest) which is a party to the Transaction.
- Transactions in which the Related Party's interest derives solely from his or her ownership of a class of equity securities of the Company and all holders of that class of equity securities received the same benefit on a pro rata basis (e.g., dividends).
- Transactions in which the Related Party's interest derives solely from his or her service as a director, trustee or officer (or similar position) of a not-for-profit organization or charity that receives donations from the Company, which donations are made pursuant to the Company's matching program, as a result of contributions by employees, that is available on the same terms to all employees of the Company.
- Compensation arrangements of any executive officer, other than an individual who is an Immediate Family Member of a Related Party, if such arrangements have been approved or recommended to the Board for approval by the Compensation Committee.
- Director compensation arrangements, if such arrangements have been approved by the Board or the Compensation Committee of the Board.
- Transactions with a Related Party in which the rates or charges involved in the Transaction are determined by competitive bids, or the Transaction involves the rendering of services as a common or contract carrier, or public utility, at rates or charges fixed in conformity with law or governmental authority.
- Indemnity payments made to directors and executive officers in accordance with the Company's then existing certificate of incorporation, bylaws and applicable laws.
- Transactions with a Related Party involving services as a bank depositary of funds, transfer agent, registrar, trustee under a trust indenture or similar services.

Pursuant to its Audit Committee charter, the Audit Committee will have the responsibility to review, approve or ratify any Related Person Transactions.

MANAGEMENT

Executive Officers and Directors

The following persons are our directors and executive officers:

Name	Age*	Position
Executive Officers		
Dr. Lynn Kirkpatrick	65	President, Chief Executive Officer and Class III Director
David Humphrey, CPA	54	Chief Financial Officer, Secretary and Treasurer
Richard Wright, MBA	50	Chief Business Officer
Geoffrey Birkett	60	Chief Commercial Officer
Linda Pestano, Ph.D.	54	Chief Development Officer
William Schmidt, Ph.D.	72	Chief Medical Officer
Jeffrey Millard, Ph.D.	47	Chief Operating Officer
Directors		
Andrew Benton, J.D.	69	Class I Director
William Chang	65	Class I Director
Bob Gower, Ph.D.	84	Class II Director and Chairman of the Board
Adam S. Levin, M.D.	43	Class III Director
Steve R. Martin	61	Class III Director
Curtis Rosebraugh, M.D., MPH	64	Class II Director
Lee Rauch	69	Class I Director

*Ages presented as of October 24, 2022

Information about our Executive Officers and Directors

Executive Officers

Dr. Lynn Kirkpatrick, Ph.D. has served as our Chief Executive Officer since January 12, 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.

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.

Richard Wright 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.

Geoffrey Birkett has served as our Chief Commercial Officer since October 1, 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.

Dr. Linda Pestano joined Ensysce in October 2021, as Chief Development Officer. Dr. Pestano has 20 years of experience developing vaccines, drugs and novel biologics for a diverse range of indications. She has worked throughout her career to guide the development of novel therapeutics to improve patient outcomes and quality of life. 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 received her Ph.D from Tufts University and undertook a Post-Doctoral Fellowship with Dana Farber Cancer Institute at the Harvard Medical School in Boston.

Dr. William K. Schmidt, Ph.D., has served as our Chief Medical Officer between January 1, 2016 and April 18, 2022 and since September 15, 2022. Between April 18, 2022 and September 15, 2022 he served as our Senior Vice President of Clinical Development. 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.

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.

Directors

Andrew Benton, J.D. has served as a member of our Board since December 2, 2019. Mr. Benton was the President, Chief Executive Officer and Trustee of Pepperdine University from June 2000 to July 2019. Mr. Benton was the former chairman of both the American Council of Education, the major coordinating body for all of the nation's higher education institutions, and the National Association of Independent Colleges and Universities. Mr. Benton is also past chair of the Association of Independent

California Colleges and Universities and a member of the American Bar Association, the Council for Higher Education Accreditation, the President's Cabinet of the West Coast Conference, the Association of Presidents of Independent Colleges and Universities, and the Los Angeles World Affairs Council. Mr. Benton holds an undergraduate degree in American studies from Oklahoma Christian University and a J.D. from Oklahoma University. Mr. Benton was awarded the Distinguished Alumnus Award by Oklahoma University. We believe that Mr. Benton's experience governing academic and other institutions qualifies him to serve on our Board.

William Chang serves as Chief Executive Officer of Westlake Realty Group and Chairman of Westlake International Group where he has worked for more than 40 years. Mr. Chang runs Edge Venture Capital Fund and is a founder and the managing partner of Digikeyih. Mr. Chang is an investor in the San Francisco Giants of Major League Baseball. Mr. Chang is also a member of YPO Gold, Northern California and is the former Chairman of U.S. Rugby Football Union. He also served on the Board of the Asia Foundation and San Francisco Port and Social Services Commissions. Mr. Chang holds a Bachelor's degree in Economics from Harvard University. We believe that Mr. Chang's experience in corporate governance qualifies him to serve on our Board.

Bob Gower, Ph.D. has served as our Chairman since 2008. Dr. Gower was Chief Executive Officer of Lyondell Petrochemical from 1985 through his retirement at the end of 1996. Together with Dr. Richard Smalley, Dr. Gower founded Carbon Nanotechnologies, Inc. (" *CNI*") in 2000 developing fullerene carbon nanotubes for multiple applications. CNI was acquired by Unidym in 2007. Dr. Gower founded Specified Fuels and Chemicals and in early 2008 and founded our company for the specific focus of using carbon nanotubes in therapeutic areas. He served on the board of directors of numerous companies, including Kirby Corporation and OmNova. In addition, Dr. Gower received his Ph.D. from the University of Minnesota. We believe that Mr. Gower's previous board and industry experience qualifies him to serve on our Board.

Adam S. Levin, MD, joined the Board in June 2021 and is the Vice Chair of Faculty Development for the Department of Orthopaedic Surgery at Johns Hopkins University, where he has been on faculty since 2014. He is an Associate Professor of Orthopaedic Surgery and Associate Professor of Oncology, researching treatments related to musculoskeletal oncology, while also maintaining an active clinical practice. He has served as the Associate Director of the Orthopaedic Surgery Residency Training Program since 2015, and has led novel curricular efforts through the Musculoskeletal Tumor Society and the American Academy of Orthopedic Surgeons. He has overseen Departmental Compliance since 2016, in addition to holding additional leadership roles related to billing, coding, and practice management for the Musculoskeletal Tumor Society and the American Academy of Orthopaedic Surgeons. Prior to joining Johns Hopkins University, Dr. Levin was an Assistant Professor of Orthopaedic Surgery at the Zucker School of Medicine at Hofstra University, and Attending Physician at Long Island Jewish Medical Center and North Shore University Hospital in New York between 2012 and 2014. From 2010 to 2012, he was a fellow of musculoskeletal oncology and Clinical Instructor at Memorial Sloan-Kettering Cancer Center, following his residency training at the North Shore/LIJ Health System (now Northwell Health) from 2005 to 2010. He was a member of the North Shore/LIJ Physician High Potential Program from 2013 until his departure in 2014, and the American Academy of Orthopaedic Surgeons' Leadership Fellows Program from 2019 to 2020; he has maintained membership in the American Orthopaedic Association of Emerging Leaders Program since 2015. Dr. Levin has also continued to serve as Associate Editor for CME for the Journal of Bone and Joint Surgery since 2016, and is on the Steering Committee for the Musculoskeletal Tumor Registry where he leads the Publications Subcommittee. Dr. Levin served as a subject-matter consultant to our predecessor, LACQ, during their initial review of our preclinical and Phase I clinical trial results. Dr. Levin holds a B.S. in Biology with a concentration in Animal Physiology from Cornell University, an M.D. from New York Medical College, and is currently studying at the Johns Hopkins University Carey School of Business for an M.B.A. with a specialization in Healthcare Management, Innovation, and Technology. We believe that Mr. Levin is well qualified to serve as a member of our Board based on his academic and practice experience and his detailed knowledge of value-based care, acute and chronic pain management, novel drug design, and health care operations and management.

Steve R. Martin has served as a member of our Board since August 2020. Mr. Martin was formerly Senior Vice President and Chief Financial Officer of Armata Pharmaceuticals, Inc., a clinical development stage biotechnology company listed on New York Stock Exchange, from January 2016 until his retirement from the position on June 30, 2022. Previously, Mr. Martin served as Senior Vice President and Chief Financial Officer of Applied Proteomics, Inc., a molecular diagnostics company, from December 2014 to August 2015. From June 2011 to December 2014, Mr. Martin served as Senior Vice President and Chief Financial Officer of Apricus Biosciences, Inc. ("*Apricus*"), a publicly traded pharmaceutical company, and served as the Interim Chief Executive Officer of Apricus from November 2012 through March 2013. From 2008 to January 2011, Mr. Martin served as Senior Vice President and Chief Financial Officer of BakBone Software (" *BakBone*"), a publicly traded software company. During his final 10 months with BakBone until the company's acquisition in January 2011, Mr. Martin also served as BakBone's Interim Chief Executive Officer. From 2005 to 2007, Mr. Martin served as Chief Financial Officer of Stratagene Corporation, a publicly traded research products and clinical diagnostics company. Mr. Martin's previous experience also includes serving as Controller with Gen-Probe Incorporated, a publicly traded molecular diagnostics company, as well as 10 years with Deloitte & Touche LLP, a public accounting firm. Mr. Martin holds a Bachelor in Science in Accounting from San Diego State University and is a certified public accountant (inactive). We believe that Mr. Martin's expertise in biopharmaceutical industry and accounting expertise qualifies him to serve on our Board.

Curtis Rosebraugh, M.D., MPH joined our Board in June 2021 and has been a member of Griebel and Rosebraugh Consulting LLC since May 2018, where he is a regulatory consultant for small molecule and biological drug development. Prior to forming a consulting firm, he was with the Food and Drug Administration since 2000 and was the Director of the Office of Drug Evaluation II ("*ODEII*") within the Center for Drug Evaluation and Research ("*CDER*") from 2007 until his retirement in 2018, with supervisory responsibility for the evaluation of all drug products within 3 divisions: the Division of Pulmonary, Allergy and Rheumatology Products, the Division of metabolism and Endocrinology Products and the Division of Anesthesia, Analgesia, and Addiction Products. He has overseen the development and approval of over 50 new drugs, was responsible for the planning of over 100 advisory committee meetings, led ODE II through several controversial safety issues and has received many honors and awards. Dr. Rosebraugh has been involved in the development of abuse deterrent opioid formulations and has also been involved in the development of the biosimilar program as well as many other CDER initiatives. Dr. Rosebraugh received his undergraduate degree in pharmacy in 1981, his Medical Degree in 1986 and completed a residency in Internal Medicine in 1989, all at the University of Kansas. He completed a Masters of Public Health at Johns Hopkins School of Public Health in 1999 and a Clinical Pharmacology Fellowship at Georgetown University in 2000. Dr. Rosebraugh joined the FDA in 2000 as a Medical Reviewer in the Division of Pulmonary and Allergy Drug Products and became the Deputy Director Office of Nonprescription Products in 2002 before joining ODE II in 2005, first as Deputy Director and then as Director in 2007. We believe that Dr. Rosebraugh's regulatory experience and overseeing and participating in drug development in the biopharmaceutical industry qualifies him to serve on our Board.

Lee Rauch has served on our Board since February 2022. She is an experienced Chief Executive Officer and Strategy Advisor, has served both public and private companies. During her near 40-year career, Ms. Rauch successful built companies ranging in focus from pre-clinical research to advanced clinical development, took the lead in mergers and acquisitions and used her experience to secure financing for public and private biotech companies. Among her many leadership roles, Ms. Rauch, was notably a founding member of McKinsey & Co.'s International Pharmaceutical Practice and the Executive Chairman of Springboard Enterprises Health Innovation Hub. Most recently, Ms. Rauch, served as President and CEO of Viridian Therapeutics, Inc. Ms. Rauch received a B.S. in Chemistry from Arizona State University and an M.B.A. in Finance from the University of Chicago. We believe that Ms. Rauch's biopharmaceutical industry experience and expertise qualifies her to serve on our Board.

Director Independence

Nasdaq listing rules require that a majority of the board of directors of a company listed on Nasdaq be composed of "*independent directors*," which is defined generally as a person other than an officer or employee of the company or its subsidiaries or any other individual having a relationship that, in the opinion of the company's board of directors, would interfere with the director's exercise of independent judgment in carrying out the responsibilities of a director. Based on information provided by each director concerning his or her background, employment and affiliations, including family relationships, the Board determined that each of Bob Gower, William Chang, Andrew Benton, Steve R. Martin, Adam S. Levin, Lee Rauch and Curtis Rosebraugh is an independent director under the Nasdaq listing rules and Rule 10A-3 of the Exchange Act. In making these determinations, the Board considered the current and prior relationships that each non-employee director has and will have with us and all other facts and circumstances that the Board deems relevant in determining independence, including the beneficial ownership of our common stock by each non- employee director (and related entities) and

the transactions involving them described in the section entitled "*Certain Relationships and Related Party Transactions.*"

Role of Board in Risk Oversight

The Board has extensive involvement in the oversight of risk management related to us and our business and accomplishes this oversight through the regular reporting to the Board by the audit committee. The audit committee represents the Board by periodically reviewing our accounting, reporting and financial practices, including the integrity of our financial statements, the surveillance of administrative and financial controls and our compliance with legal and regulatory requirements. Through its regular meetings with management, including the finance, legal, internal audit and information technology functions, the audit committee reviews and discuss all significant areas of our business and summarize for the Board all areas of risk and the appropriate mitigating factors. In addition, our Board receives periodic detailed operating performance reviews from management.

Composition of the Board

Our business and affairs are managed under the direction of the Board. Our Board consists of eight directors, which are divided into three classes (Class I, II and III) with Class I and III each consisting of three directors and Class II consisting of two directors.

Board Committees

The standing committees of our Board consist of an audit committee, a compensation committee and a nominating and corporate governance committee. Our Board may from time to time establish other committees. Each of the committees reports to the Board.

Our president and chief executive officer and other executive officers regularly report to the non-executive directors and the audit, the compensation and the nominating and corporate governance committees to ensure effective and efficient oversight of our activities and to assist in proper risk management and the ongoing evaluation of management controls.

Audit Committee

We have an audit committee consisting of Steve R. Martin, who serves as the chairperson, Bob Gower and Andrew Benton. Each member of the audit committee qualifies as an independent director under the Nasdaq corporate governance standards and the independence requirements of Rule 10A-3 of the Exchange Act. Our Board has determined that Steve R. Martin qualifies as an "*audit committee financial expert*" as such term is defined in Item 407(d)(5) of Regulation S-K and possesses financial sophistication, as defined under the rules of Nasdaq.

The purpose of the audit committee is to prepare the audit committee report required by the SEC to be included in our proxy statement and to assist our Board in overseeing and monitoring (1) the quality and integrity of our financial statements, (2) our compliance with legal and regulatory requirements, (3) our independent registered public accounting firm's qualifications and independence, (4) the performance of our internal audit function and (5) the performance of our independent registered public accounting firm.

Our Board adopted a written charter for the audit committee, which is be available on our website.

Compensation Committee

We have a compensation committee consisting of Adam Levin, who serves as the chairperson, Bob Gower, William Chang, and Lee Rauch.

The purpose of the compensation committee is to assist our Board in discharging its responsibilities relating to (1) setting our compensation program and compensation of our executive officers and directors, (2) monitoring our incentive and equity-based compensation plans and (3) preparing the compensation committee report, if required to be included in our proxy statement under the rules and regulations of the SEC.

Our Board adopted a written charter for the compensation committee, which is available on our website.

Nominating and Corporate Governance Committee

We have a nominating and corporate governance committee, consisting of Lee Rauch, who serves as chairperson, Bob Gower, Steve R. Martin and Curtis Rosebraugh. The purpose of our nominating and corporate governance committee is to assist our Board in discharging its responsibilities relating to (1) identifying individuals qualified to become new Board members, consistent with criteria approved by the Board, (2) reviewing the qualifications of incumbent directors to determine whether to recommend them for reelection and selecting, or recommending that the Board select, the director nominees for the next annual meeting of stockholders, (3) identifying Board members qualified to fill vacancies on any Board committee and recommending that the Board appoint the identified member or members to the applicable committee, (4) reviewing and recommending to the Board corporate governance principles applicable to us, (5) overseeing the evaluation of the Board and management and (6) handling such other matters that are specifically delegated to the committee by the Board from time to time.

Our Board adopted a written charter for the nominating and corporate governance committee, which is available on our website.

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(a) and (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.

EXECUTIVE & DIRECTOR COMPENSATION

Ensysce

References in this section to "we," "our," "us," "the Company" or "Ensysce" generally refer to Ensysce and its consolidated subsidiaries.

This section discusses the material components of the executive compensation program for our named executive officers. Our named executive officers, consisting of our principal executive officer and the next two most highly compensated executive officers, for the year ended December 31, 2021, were:

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

- David Humphrey, CPA, Chief Financial Officer; and
- Geoff Birkett, Chief Commercial Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt in the future may differ materially from the currently planned programs summarized in this discussion.

Summary Compensation Table

The following table sets forth information concerning the compensation earned by our NEOs in respect of our fiscal years ended December 31, 2021 and December 31, 2020.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Dr. Lynn Kirkpatrick, PhD.							
Chief Executive Officer	2021	174,149	114,000(1)	-	-	-	288,149
	2020	155,868	-	-	-	-	155,868
David Humphrey							
Chief Financial Officer(2)	2021	187,643	96,000(1)	-		-	283,643
	2020	-	-	-	-	-	-
Geoff Birkett							
Chief Commercial Officer	2021	135,000	-	-	-	-	135,000
	2020	72,000	-	-	-	-	72,000

(1) Amounts shown are discretionary cash bonuses earned in respect of 2021 performance and were paid in the first quarter of 2022. See *"— Annual Performance-Based Bonuses"* for more information regarding bonus awards made to Dr. Kirkpatrick and Mr. Humphrey for the fiscal year ended December 31, 2021.

(2) Mr. Humphrey commenced employment with the Company on February 12, 2021.

Narrative Disclosure to Summary Compensation Table

Elements of Compensation in 2021

The compensation of our NEOs generally consists of base salary, annual cash bonus opportunities and long-term incentive compensation in the form of equity awards, as described below.

Base Salary

The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role, responsibilities, and contributions. Base salaries were initially set at the time each NEO commenced employment with us, are reviewed annually and may be increased based on the individual performance of the NEO, company performance, any change in the executive's position within our business, the scope of the executive's responsibilities and any changes thereto. As of December 31, 2021, the NEOs' annual base salary rates were: $380,000 for Dr. Kirkpatrick, $320,000 for Mr. Humphrey and $300,000 for Mr. Birkett.

Effective March 1, 2022, the NEO's annual base salary rates increased to $395,000 for Dr. Kirkpatrick, $330,000 for Mr. Humphrey and $305,000 for Mr. Birkett.

Annual Performance-Based Bonuses

Dr. Kirkpatrick and Mr. Humphrey each received a performance-based cash bonus for 2021, paid in early 2022. The Board based the bonus awards primarily on our successful completion of the merger (the "*Merger*") with Leisure Acquisition Corp. ("*LACQ*") with $8 million of financing, raising $15 million in additional financing through convertible notes, and continued progress on clinical trials. The Board also considered the target bonus amount of 30% of base salary for Mr. Humphrey included in his employment offer letter.

Starting in 2022, each of our NEOs' performance-based cash bonus opportunity will be expressed as a percentage of base salary that can be achieved at a target level by meeting predetermined Company performance objectives established by the Board or the Compensation Committee. The 2022 annual bonus for Dr. Kirkpatrick is targeted at 50% of her base salary, and Mr. Humphrey and Mr. Birkett's 2022 annual bonuses are targeted at 30% of their respective base salary.

Long-Term Equity Incentives

In 2021, the Company maintained the Ensysce Biosciences, Inc. 2021 Omnibus Incentive Plan (the "*2021 Plan*") to provide equity-based incentive awards, designed to align our interests and the interests of our stockholders with those of our employees and consultants, including our NEOs. No stock or option awards were granted in 2021 to our NEOs.

On January 26, 2022, our stockholders approved the 2021 Amended and Restated Plan. All grants effectuated under predecessor equity plans were converted to grants outstanding under the 2021 Amended and Restated Plan.

Employment Agreements with our NEOs

Dr. Lynn Kirkpatrick, Ph.D.

In September 2021, we entered into a formal employment offer letter with Dr. Kirkpatrick. The offer letter provides for Dr. Kirkpatrick's at-will employment as our Chief Executive Officer and sets forth her annual base salary of $380,000. Additionally, the letter provides for her initial target annual bonus opportunity of up to 50% of base salary, with such bonus system and performance period commencing in 2022. The offer letter also indicates that Dr. Kirkpatrick is eligible to be granted certain stock awards under our equity incentive plan.

Dr. Kirkpatrick's offer letter provides for severance benefits upon a termination of her employment by the Company without "*cause*", or upon her resignation for "*good*

reason", in an amount equal to twelve (12) months of her then current base salary (ignoring any decrease in base salary that forms the basis for good reason); provided, however, that the payment of such benefits is subject to Dr. Kirkpatrick's continued compliance with her obligations under her "*At-Will, Confidential Information and Assignment of Inventions Agreement*" and her execution of a general release of claims. Additionally, if such termination without cause or for good reason occurs within the one (1) month prior to, or during the twelve (12) month period immediately following a change in control, then all outstanding equity awards subject to time-based vesting will become fully vested on the later of Dr. Kirkpatrick's termination date and the change in control. Cause and good reason are as defined in Dr. Kirkpatrick's offer letter.

Dave Humphrey

In February 2021, we entered into an employment offer letter with Mr. Humphrey. The offer letter provides for Mr. Humphrey's at-will employment as our Chief Financial Officer and sets forth his initial base salary of $6,000 per month until the completion of the Merger and an annual base salary of $320,000 thereafter. Additionally, the letter provides for his initial target annual bonus opportunity of up to 30% of his full $320,000 base salary. The offer letter also provides for a grant of restricted stock units of 2,500 Company shares, to vest over a three (3) year period, with 1,000 vesting on December 15, 2021 and 750 vesting on December 15, 2022 and December 15, 2023. This award of restricted stock units was formally granted on February 9, 2022, with the first 1,000 shares being immediately vested and paid. Additionally, Mr. Humphrey's offer letter provided for the issuance of an option to purchase 1% of our fully diluted common stock, or 13,750 shares of common stock. This option was formally granted on February 4, 2022, following stockholder approval of the 2021 Amended and Restated Plan, with an exercise price of $62.60 per share (which was greater than the then-current per share price) and was set to vest over a four-year period, with 25% of the common stock underlying the option vesting on February 11, 2022 and 75% of the common stock underlying the option vesting in 36 equal monthly installments thereafter, subject to Mr. Humphrey's continued employment.

Mr. Humphrey's offer letter provides for severance benefits upon a termination of his employment by the Company without "*cause*", or upon his resignation for "*good reason*", in an amount equal to six (6) months of his then current base salary (ignoring any decrease in base salary that forms the basis for good reason); provided, however, that the payment of such benefits is subject to Mr. Humphrey's continued compliance with his obligations under his "*Confidential Information and Assignment Agreement*" and his execution of a general release of claims. Additionally, if such termination without cause or for good reason occurs within the one (1) month prior to, or during the twelve (12) month period immediately following a change in control, then all outstanding equity awards subject to time-based vesting will become fully vested on the later of Mr. Humphrey's termination date and the change in control. Cause and good reason are as defined in Mr. Humphrey's offer letter.

Geoff Birkett

In July 2021, we entered into a formal employment offer letter with Mr. Birkett. The offer letter provides for Mr. Birkett's at-will employment as our Chief Commercial Officer and sets forth his annual base salary of $300,000. Additionally, the letter provides for his initial target annual bonus opportunity of up to 30% of base salary, with such bonus system and performance period commencing in 2022. The offer letter also indicates that Mr. Birkett is eligible to be granted certain stock awards under our equity incentive plan following his start date.

Mr. Birkett's offer letter provides for severance benefits upon a termination of his employment by the Company without "cause", or upon his resignation for "good reason", in an amount equal to three (3) months of his then current base salary (ignoring any decrease in base salary that forms the basis for good reason); provided, however, that the payment of such benefits is subject to Mr. Birkett's continued compliance with his obligations under his "*Confidential Information and Assignment Agreement*" and his execution of a general release of claims. Additionally, if such termination without cause or for good reason occurs within the one (1) month prior to, or the twelve (12) month period immediately following a change in control, then all outstanding equity awards subject to time-based vesting will become fully vested on the later of Mr. Birkett's termination date and the change in control. Cause and good reason are as defined in the offer letter.

At-Will, Confidential Information and Assignment of Inventions Agreement

In connection with each's respective offer letter, Dr. Kirkpatrick, Mr. Birkett and Mr. Humphrey entered into an "At-Will, Confidential Information and Assignment of Inventions Agreement" (the "Confidentiality Agreement"). The Confidentiality Agreements include customary prohibitions against solicitation of our customers and employees, both during employment and for two (2) years following any cessation of employment. The Confidentiality Agreements also include standard provisions relating to the Company's intellectual property rights and prohibit the executive from disclosing confidential information. The Confidentiality Agreements are incorporated by reference into the offer letters and payment of any severance benefits under each executive's offer letter is conditioned on continued compliance with his or her Confidentiality Agreement.

Other Benefits

We currently provide welfare benefits that are available to all of our employees, including our NEOs, including health, dental, vision and group life insurance.

Prior to 2022, we maintained the Ensysce Biosciences, Inc. Retirement Trust, effective January 1, 2005, a tax-qualified profit sharing plan established for the exclusive benefit of our eligible employees. However, no employees participated in the plan as of December 31, 2021. Effective January 1, 2022, the Ensysce Biosciences, Inc. Retirement Trust, renamed the "Ensysce Biosciences, Inc. 401(k) Plan" (the "*401(k) Plan*"), was amended and restated. The 401(k) Plan provides eligible employees with an opportunity to save for retirement on a tax-advantaged basis and under which we are permitted to make safe harbor employer contributions. Employees' pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) Plan is intended to be qualified under Section 401(a) of the Code, with the related trust intended to be tax exempt under Section 501(a) of the Code. Under the 401(k) Plan, we make employer contributions to all employees – regardless of an employee's contributions (or lack thereof) – in an amount equal to 3% of the employee's eligible compensation. Dr. Kirkpatrick and Mr. Humphrey commenced employee contributions to the 401(k) Plan at the beginning of 2022. To date, Mr. Birkett has not contributed to the 401(k) Plan.

We do not maintain any defined benefit pension plans or nonqualified deferred compensation plans.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information regarding outstanding equity awards held by our NEOs as of December 31, 2021.

		Option Awards				Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested ($)
Dr. Lynn Kirkpatrick, PhD.	12/31/2015	4,997	0	64.20	12/21/2022	-	-
	12/31/2015	499	0	64.20	12/21/2022	-	-

	1/15/2016	13,170	0	63.80	1/15/2026	-	-
	1/4/2017	23,047	0	36.60	1/4/2027	-	-
	2/5/2018	40,878	0	33.60	2/5/2028	-	-
	3/1/2019	32,925	0	51.80	2/28/2029	-	-
	3/15/2019	329	0	51.80	3/14/2029	-	-
Dave Humphrey	-	-	-	-	-	-	-
Geoff Birkett	10/1/2018	987	0	51.80	9/30/2028	-	-
	3/1/2019	16,462	0	51.80	2/28/2029	-	-

Director Compensation

For the year ended December 31, 2021, we did not grant equity compensation to our non-employee directors for their service on our Board.

The following table provides summary information concerning compensation paid or accrued by us to or on behalf of our non-employee directors for services rendered to us as of December 31, 2021.

Name	Fees Earned or Paid in Cash ($)	Total ($)
Bob Gower	6,250	6,250
William Chang	1,875	1,875
Andrew Benton	1,875	1,875
Steve Martin	3,750	3,750
Adam Levin	2,500	2,500
Curt Rosebraugh	1,875	1,875

In November 2021, the Board approved a stock option award to purchase 1,000 shares of our common stock for each of the six (6) non-executive directors, conditioned on stockholder approval of the 2021 Amended and Restated Plan, with 100% of the option vesting on the date of the Company's first routine annual stockholder meeting in 2022 at which directors are elected. The options were formally granted on February 4, 2022, shortly after stockholder approval of the 2021 Amended and Restated Plan. Each of these options has a ten (10) year term and an exercise price equal to $62.60 per share, which was greater than the fair market value of our common stock upon the grant date.

DESCRIPTION OF CAPITAL STOCK

The following summary of the material terms of our common stock and description of certain of our other securities is not intended to be a complete summary of the rights and preferences of our common stock or such other securities. We urge you to read the third amended and restated certificate of incorporation in its entirety for a complete description of the rights and preferences of our common stock. See "*Where You Can Find More Information.*"

Pursuant to the third amended and restated certificate of incorporation, our authorized capital stock consists of 250,000,000 shares of common stock, $0.0001 par value, and 1,500,000 shares of undesignated preferred stock, $0.0001 par value.

Common Stock

As of November 14, 2022, 2,841,091 shares of our common stock were issued and outstanding.

Common stockholders of record are entitled to one vote for each share held on all matters to be voted on by stockholders. Unless specified in our amended and restated certificate of incorporation or bylaws, or as required by applicable provisions of the DGCL or applicable stock exchange rules, the affirmative vote of a majority of our shares of common stock that are voted is required to approve any such matter voted on by our stockholders. Our Board is divided into three classes, each of which will generally serve for a term of three years with only one class of directors being elected in each year. There is no cumulative voting with respect to the election of directors or any other matter, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of the directors. Our stockholders are entitled to receive ratable dividends when, as and if declared by the Board out of funds legally available therefor.

In the event of a liquidation, dissolution or winding up, our stockholders are entitled to share ratably in all assets remaining available for distribution to them after payment of liabilities and after provision is made for each class of stock, if any, having preference over the common stock. Our stockholders have no preemptive or other subscription rights. There are no sinking fund provisions applicable to the common stock.

Certain Anti-Takeover Provisions of our Third Amended and Restated Certificate of Incorporation and our Bylaws

The third amended and restated certificate of incorporation and our bylaws contain provisions that may delay, defer or discourage another party from acquiring control of us. These provisions, which are summarized below, discourage coercive takeover practices or inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board, which may result in an improvement of the terms of any such acquisition in favor of our stockholders. However, they also give the Board the power to discourage acquisitions that some stockholders may favor.

Classified Board

Our third amended and restated certificate of incorporation provides that our Board is classified into three classes of directors. As a result, in most circumstances, a person can gain control of our Board only by successfully engaging in a proxy contest at two or more annual meetings.

Authorized but Unissued Shares

Our authorized but unissued shares of common and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. However, the listing requirements of the Nasdaq, which apply if and so long as our common stock remains listed on the Nasdaq, require stockholder approval of certain issuances equal to or exceeding 20% of the then outstanding voting power or then outstanding number of shares of common stock. Additional shares that may be used in the future may be issued for a variety of corporate purposes, including future public offerings, to raise additional capital, or to facilitate acquisitions. The existence of authorized but unissued and unreserved common stock and preferred stock could render it more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Special Meetings of Stockholders

Our bylaws provide that special meetings of our stockholders may be called only by a majority vote of our Board.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our bylaws provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely, a stockholder's notice will need to be received by the company secretary at our principal executive offices not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the anniversary date of the immediately preceding annual meeting of stockholders. Pursuant to Rule 14a-8 of the Exchange Act, proposals seeking inclusion in our annual proxy statement must comply with the notice periods contained therein. Our bylaws also specify certain requirements as to the form and content of a stockholders meeting. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

Amendment of Charter or Bylaws

The amendment, alteration or repeal of the provisions of the third amended and restated certificate of incorporation governing limitation of director liability, indemnification and advancement of expenses or the adoption of any provision or bylaw inconsistent with those provisions may only be effected by the affirmative vote of the stockholders holding at least sixty five percent (65%) of the voting power of our outstanding shares entitled to vote generally in the election of directors, voting together as a single class, at a meeting of the stockholders called for that purpose. The affirmative vote of the stockholders holding at least 65% of the voting power of all outstanding shares of our capital stock is required for any amendment of the indemnification provisions in the bylaws or adoption of a provision inconsistent with them.

Exclusive Forum

Under our charter, unless we consent in writing to the selection of an alternative forum, subject to certain limitations, the sole and exclusive forum will be the Court of Chancery of the State of Delaware (or, if such court does not have jurisdiction, the Superior Court of the State of Delaware, or, if the Superior Court of the State of Delaware also does not have jurisdiction, the United States District Court for the District of Delaware) for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders;
- any action asserting a claim against us arising pursuant to any provision of the DGCL, our charter or our bylaws (as either may be amended, restated, modified, supplemented or waived from time to time);
- any action to interpret, apply, enforce or determine the validity of our charter or our bylaws; and
- any action asserting a claim against us governed by the internal affairs doctrine.

For the avoidance of doubt, the foregoing provisions of our charter will not apply to any action or proceeding asserting a claim under the Securities Act or the Exchange Act. These provisions of our charter could limit the ability of our stockholders to obtain a favorable judicial forum for certain disputes with us or with our current or former directors, officers or other employees, which may discourage such lawsuits against us and our current or former directors, officers and employees. Alternatively, if a court were to find these provisions of our charter inapplicable to, or unenforceable in respect of, one or more of the types of actions or proceedings listed above, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition and results of operations.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the Delaware General Corporation Law (sometimes referred to as Section 203) regulating corporate takeovers. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging, under specified circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares of voting stock outstanding (but not the outstanding voting stock owned by the stockholder)(1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting securities. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors do not approve in advance. We also anticipate that Section 203 may also discourage attempts that might result in a premium over the market price for the shares of our common stock held by stockholders.

The provisions of Delaware law, our certificate of incorporation and our bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Previously Issued Warrants

Prior Warrants

On September 24, 2021, we entered into the 2021 Securities Purchase Agreement, whereby we issued to the Selling Security holders warrants to purchase 54,174 shares of the common stock in the aggregate (the "*2021 Prior Warrants*") in closings on September 24, 2021 and November 5, 2021. The 2021 Prior Warrants had an exercise price of $152.60, a 30% premium to the conversion price, and are exercisable for five years following issuance. As a result of our entering into the 2022 Securities Purchase Agreement, the exercise price of the 2021 Prior Warrants was reduced to $15.60. Our obligations under the 2021 Prior Warrants are secured by all of our and our subsidiaries' assets and are guaranteed jointly and severally by our subsidiaries.

On July 1, 2022 and August 8, 2022, we completed closings under the 2022 Securities Purchase Agreement, whereby we issued to the Selling Security holders signatory

thereto warrants (the “2022 Prior Warrants”) to purchase 466,788 shares of the common stock in the aggregate. The 2022 Prior Warrants have an exercise price of $14.17, a 30% premium to the conversion price, and are exercisable for five years following issuance. Our obligations under the Prior Warrants are secured by all of our and our subsidiaries’ assets and are guaranteed jointly and severally by our subsidiaries.

Other Warrants

Over time, we have issued, to a number of third parties, warrants that may be exercised for common stock. Some of these warrants are traded on the OTC Pink Open Market under the symbol “*ENSCW*”.

Convertible Promissory Notes

2021 Secured Convertible Promissory Notes

On September 24, 2021, we entered into a securities purchase agreement (the “*2021 Securities Purchase Agreement*”) whereby we issued to the Selling Securityholders signatory thereto the 2021 Notes in the aggregate principal amount of $15.9 million for an aggregate purchase price of $15 million. Our obligations under the 2021 Securities Purchase Agreement are secured by all of our and our subsidiaries’ assets and are guaranteed jointly and severally by our subsidiaries.

We have registered with the SEC the resale of the shares of common stock issuable upon conversion of the 2021 Notes, as well as the shares of common stock issuable upon the exercise of the 2021 Prior Warrants (as defined below). The remaining balance of the 2021 Notes was repaid in October 2022.

2022 Secured Convertible Promissory Notes

On June 30, 2022, we entered into a securities purchase agreement (the “*2022 Securities Purchase Agreement*”) whereby we issued to the Selling Security holders signatory thereto the 2022 Notes in the aggregate principal amount of $8.48 million for an aggregate purchase price of $8.0 million in two closings under the 2022 Securities Purchase Agreement, the first closing occurring on July 1, 2022 and the second occurring on August 8, 2022. Our obligations under the 2022 Securities Purchase Agreement are secured by all of our and our subsidiaries’ assets and are guaranteed jointly and severally by our subsidiaries.

The 2022 Notes, subject to an original issue discount of six percent (6%), have a term of eighteen months and accrue interest at the rate of 6.0% per annum. The 2022 Notes are convertible into the common stock, at a per share conversion price equal to $10.90, a 10% premium to the average price of the common stock for the three trading days prior to the first closing under the 2022 Securities Purchase Agreement. The conversion price is subject to customary anti-dilution adjustments upon (among other triggering events) the occurrence of a change of control transaction and certain dilutive transactions, including subsequent equity issuances, share dividends and splits occurring following the issuance of the promissory note.

Under the 2022 Notes, commencing on September 29, 2022 and continuing monthly on the first day of each month beginning November 1, 2022, we are obligated to redeem one fifteenth (1/15th) of the original principal amount of the applicable 2022 Notes, plus accrued but unpaid interest, liquidated damages and any other amounts then owing to the holder of such 2022 Note. Under the 2022 Notes issued on August 8, 2022, commencing on November 1, 2022 and continuing monthly on the first day of each month beginning December 1, 2022, we are obligated to redeem one fifteenth (1/15th) of the original principal amount under the applicable 2022 Note, plus accrued but unpaid interest, liquidated damages and any other amounts then owing to the holder of such 2022 Note.

We may elect to pay all or part of the redemption amount in cash with a premium of eight percent or in conversion 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 2022 Securities Purchase Agreement) 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 $2.006 and certain equity conditions are satisfied. We may incur additional dilution from repayment of the 2022 Notes in common stock or re-setting the conversion price of the 2022 Notes if we issue equity at a price below the conversion price of the 2022 Notes.

We have registered with the SEC the resale of the shares of common stock issuable upon conversion of the 2022 Notes as well as the shares of common stock issuable upon the exercise of the warrants issued under the 2022 Securities Purchase Agreement (the “*2022 Prior Warrants*”). The 2022 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 under the 2022 Notes are secured by all of our and our subsidiaries’ assets and are guaranteed jointly and severally by our subsidiaries.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering 5,274,261 shares of our common stock assuming a combined public offering price of $2.37 per share and accompanying warrants (the last reported sale price of our common stock on Nasdaq on November 14, 2022). We are also offering pre-funded warrants to those purchasers whose purchase of shares of our common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock following the consummation of this offering in lieu of the shares of common stocks that would result in such excess ownership. For each pre-funded warrant we sell, the number of shares of common stock we sell in this offering will be decreased on a one-for-one basis. Each share of our common stock (or pre-funded warrant in lieu of a share of common stock) is being sold together with a Series A warrant to purchase one share of our common stock and a Series B warrant to purchase one share of our common stock. The shares of our common stock and related warrants will be issued separately. We are also registering the shares of our common stock issuable from time to time upon exercise of the pre-funded warrants and the warrants offered hereby.

Common Stock

The material terms and provisions of our common stock are described under the caption “*Description of Capital Stock*” in this prospectus and are incorporated herein by reference.

Warrants

The following summary of certain terms and provisions of the Series A warrants and Series B warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of warrants, the forms of which are filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the forms of warrant for a complete description of the terms and conditions of the warrants.

Duration and Exercise Price

Each warrant offered hereby will have an exercise price of $ per share (or 100% of the combined public offering price per share and accompanying warrants). The Series A warrants will be immediately exercisable and may be exercised until five years from the date of issuance. The Series B warrants will be immediately exercisable and may be exercised until six months from the date of issuance. The exercise price and number of shares of common stock issuable upon exercise of the warrants is subject to

appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The warrants will be issued separately from the common stock or pre-funded warrants, respectively, and may be transferred separately immediately thereafter. The warrants will be issued in certificated form only.

Exercisability

The warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of such holder's warrants to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise

If, at the time a holder exercises its warrants, a registration statement registering the issuance or resale of the shares of common stock underlying the warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the warrant.

Fundamental Transactions

In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our shares of common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of the voting power represented by our outstanding shares of capital stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding shares of capital stock, In the event of any fundamental transaction, as described in the warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our common stock, then upon any subsequent exercise of a warrant, the holder will have the right to receive as alternative consideration, for each share of our common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of our common stock for which the warrant is exercisable immediately prior to such event. Notwithstanding the foregoing, in the event of a fundamental transaction, the holders of the warrants have the right to require us or a successor entity to redeem the warrants for cash in the amount of the Black-Scholes Value (as defined in each warrant) of the unexercised portion of the warrants concurrently with or within 30 days following the consummation of a fundamental transaction.

However, in the event of a fundamental transaction which is not in our control, including a fundamental transaction not approved by our board of directors, the holders of the warrants will only be entitled to receive from us or our successor entity, as of the date of consummation of such fundamental transaction the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of the warrant that is being offered and paid to the holders of our common stock in connection with the fundamental transaction, whether that consideration is in the form of cash, stock or any combination of cash and stock, or whether the holders of our common stock are given the choice to receive alternative forms of consideration in connection with the fundamental transaction.

Transferability

Subject to applicable laws, a warrant may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the next whole share or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Trading Market

There is no established trading market for the warrants, and we do not expect such a market to develop. We do not intend to apply to list the warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the warrants will be extremely limited.

Right as a Stockholder

Except as otherwise provided in the warrants or by virtue of the holder's ownership of shares of our common stock, such holder of warrants does not have the rights or privileges of a holder of our common stock, including any voting rights, until such holder exercises such holder's warrants. The warrants will provide that the holders of the warrants have the right to participate in distributions or dividends paid on our shares of common stock.

Waivers and Amendments

The Series A warrants and the Series B warrants may be modified or amended or the provisions of such warrants waived with our consent and the consent of the holders of at least a majority of the outstanding warrants of the Series A warrants or the Series B warrants, as applicable.

Pre-funded Warrants

The following summary of certain terms and provisions of the pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Duration and Exercise Price

Each pre-funded warrant offered hereby will have an initial exercise price per share of common stock equal to $0.0001. The pre-funded warrants will be immediately exercisable and will expire when exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of share dividends, share splits, reorganizations or similar events affecting our shares of common stock and the exercise price.

Exercisability

The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% of the outstanding shares of common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of beneficial ownership of outstanding shares after exercising the holder's pre-funded warrants up to 9.99% of the number of our shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. Purchasers of pre-funded warrants in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding shares of common stock.

Cashless Exercise

In lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the pre-funded warrants. Rather, at the Company's election, the number of shares of common stock to be issued will be rounded up to the next whole share or the Company will pay a cash adjustment in an amount equal to such fraction multiplied by the exercise price.

Transferability

Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrants to us together with the appropriate instruments of transfer.

Trading Market

There is no established trading market for the warrants, and we do not expect such a market to develop. We do not intend to apply to list the pre-funded warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants will be extremely limited.

Right as a Shareholder

Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our shares of common stock, including any voting rights, until they exercise their pre-funded warrants. The pre-funded warrants will provide that the holders of the pre-funded warrants have the right to participate in distributions or dividends paid on our shares of common stock.

Fundamental Transaction

In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our shares of common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of the voting power represented by our outstanding shares of capital stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding shares of capital stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction on a net exercise basis.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information with respect to the beneficial ownership of shares of our common stock by (i) each director, (ii) each named executive officer, (iii) all directors and executive officers as a group, and (iv) each person who we know beneficially owns more than 5% of our common stock as of November 14, 2022, unless otherwise indicated below.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include shares of common stock issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days after November 14, 2022 but excludes unvested stock options. Except as otherwise indicated, all of the shares reflected in the table are shares of common stock and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed outstanding shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of November 14, 2022. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Percentage ownership calculations for beneficial ownership for each person or entity are based on 2,841,091 shares outstanding as of November 14, 2022. Except as otherwise indicated in the table below, addresses of named beneficial owners are in care of Ensysce Biosciences, Inc., 7946 Ivanhoe Avenue, Suite 201, La Jolla, California 92037.

Beneficial Ownership Table

Name and Address of Beneficial Owners	Number of Shares	Percentage
Officers and Directors		
Dr. Lynn Kirkpatrick (1)	134,938	4.6%
Geoff Birkett (2)	17,449	*
David Humphrey (3)	8,338	*
Linda Pestano (4)	2,916	*
Andrew Benton (5)	4,575	*
William Chang (6)	131,157	4.6%

Bob Gower (7)	397,656	14.0%
Adam Levin (8)	1,375	*
Steve R. Martin (9)	4,026	*
Lee Rauch (10)	680	*
Curtis Rosebraugh (11)	1,375	*
All directors and named executive officers as a group (eleven individuals)	704,485	23.5%
All		
Greater than 5% Holders		
Bob Gower (7)	397,656	14.0%
HG Vora Capital Management, LLC (12)	356,500	11.7%
A. Lorne Weil and affiliated entities (13)	150,138	5.1%

* Indicates less than 1%

(1) Includes 115,845 shares subject to options.

(2) Consists of shares subject to options.

(3) Consists of 6,588 shares subject to options and 1,750 shares of restricted stock.

(4) Consists of shares subject to options.

(5) Consists of shares subject to options.

(6) Includes 1,375 shares subject to options, 37,515 shares owned directly by Mr. Chang and his wife and 92,267 shares owned through trusts in which Mr. Chang has sole or shared voting and dispositive power. Does not include 5,000 shares held by trusts for family members in which Mr. Chang does not have beneficial ownership. The business address for Mr. Chang is 520 El Camino Real, 9th Floor, San Mateo, CA 94402.

(7) Includes 1,704 shares subject to options. The business address for Mr. Gower is 101 Westcott, Unit 303, Houston, Texas 77007.

(8) Consists of shares subject to options.

(9) Consists of shares subject to options.

(10) Consists of shares subject to options.

(11) Consists of shares subject to options.

(12) Based on a Schedule 13G/A filed with the SEC on February 14, 2022 by HG Vora Capital Management, LLC, which lists its business address as 330 Madison Avenue, 20th Floor, New York, New York 10017.

(13) Based on a Schedule 13G/A filed with the SEC on July 7, 2021 by Hydra LAC, LLC and Mr. Weil. Represents 13,345 shares held of record my Mr. Weil and 43,393 shares held of record by Hydra LAC, LLC, and 36,505 warrants held of record by Mr. Weil, 50,000 warrants held of record by Hydra LAC, LLC and 6,895 warrants held by Hydra Management LLC, which warrants became exercisable on July 30, 2021. Mr. Weil is the managing member of Hydra LAC, LLC and the sole member of Hydra Management LLC and disclaims beneficial ownership with respect to the securities except to the extent of his pecuniary interest therein. The business address of Mr. Weil is 250 West 57th Street, Suite 415, New York, NY 10107.

UNDERWRITING

We have entered into an underwriting agreement with Lake Street Capital Markets, LLC, or Lake Street, or the underwriter, with respect to the shares of common stock, pre-funded warrants, Series A warrants and Series B warrants subject to this offering. Subject to certain conditions, we have agreed to sell to the underwriter, and the underwriter has agreed to purchase, all of the shares of common stock, pre-funded warrants and Series A warrants and Series B warrants offered hereby (other than securities covered by the over-allotment option described below).

The underwriter is offering the shares of common stock, pre-funded warrants, Series A warrants and Series B warrants subject to its acceptance of the shares of common stock, pre-funded warrants, Series A warrants and Series B warrants from us and subject to prior sale. The underwriting agreement provides that the obligation of the underwriter to pay for and accept delivery of the shares of common stock, pre-funded warrants, Series A warrants and Series B warrants offered by this prospectus are subject to the approval of certain legal matters by its counsel and to certain other conditions. The underwriter is obligated to take and pay for all of the shares of common stock, pre-funded warrants, Series A warrants and Series B warrants if any such shares, pre-funded warrants, Series A warrants and Series B warrants are taken. However, the underwriter is not required to take or pay for the securities covered by the underwriter's over-allotment option described below.

Certain of our existing stockholders, including certain affiliates of our directors, have indicated an interest in purchasing an aggregate of approximately $500,000 of our securities in this offering at the combined public offering price per share and accompanying warrants. However, because indications of interest are not binding agreements or commitments to purchase, the underwriter may determine to sell more, less or no securities in this offering to any of these stockholders, or any of these stockholders may determine to purchase more, less or no securities in this offering.

Over-Allotment Option

We have granted the underwriter an option, exercisable for 45 days from the date of this prospectus, to purchase up to 791,139 additional shares of common stock and/or additional Series A warrants and/or Series B warrants, in any combination thereof, to cover over-allotments, if any, of the securities offered by this prospectus. The purchase price to be paid by the underwriter per additional share of common stock will be $, less underwriting discounts and commissions, the purchase price to be paid by the underwriter per additional Series A warrant will be $0.01, less underwriting discounts and commissions, and the purchase price to be paid by the underwriter per additional Series B warrant will be $0.01, less underwriting discounts and commissions. If the underwriter exercises this option, the underwriter will be obligated, subject to certain conditions, to purchase such number of additional shares and/or warrants. Because the warrants are not listed on a national securities exchange or other nationally recognized trading market, the underwriter will be unable to satisfy any over-allotment of shares and warrants without exercising the underwriter's over-allotment option with respect to the warrants. As a result, the underwriter has informed us that it intends to exercise its over-allotment option for all of the warrants which are over-allotted, if any, at the time of the initial offering of the shares and the warrants. However, because our common stock is publicly traded, the underwriter may satisfy some or all of the over-allotment of shares of our common stock, if any, by purchasing shares in the open market and will have no obligation to exercise the over-allotment option with respect to our common stock. If the underwriter exercises its over-allotment option with respect to the warrants in full, but does not exercise its over-allotment option with respect to our common stock, then the effective warrant coverage for each share of common stock sold in this offering would be 230% instead of the 200% stated on the cover page of this prospectus.

Discount, Commissions and Expenses

The underwriter has advised us that it proposes to offer the shares of common stock or pre-funded warrants and the accompanying Series A warrants and Series B warrants to the public at the combined public offering prices set forth on the cover page of this prospectus and to certain dealers at those prices less a concession not in excess of $ per share of common stock (or pre-funded warrant) and accompanying warrants. The underwriter may allow, and certain dealers may reallow, a discount from the concession not in excess of $ per share of common stock (or pre-funded warrant) and accompanying warrants to certain brokers and dealers. After this offering, the public offering price, concession and reallowance to dealers may be changed by the underwriter. No such change will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the underwriting discount payable to the underwriter by us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriter's over-allotment option to purchase additional shares of common stock and/or Series A warrants and/or Series B warrants.

	Per Share and Accompanying Warrants	Per Pre-Funded Warrant and Accompanying Warrants	Total Without Exercise of Over-Allotment Option	Total With Exercise of Over-Allotment Option
Combined Public Offering Price	$	$	$	$
Underwriting Discount	$	$	$	$

We have agreed to reimburse the underwriter for certain out-of-pocket expenses, including the fees and disbursements of its counsel, up to an aggregate of $200,000. We estimate that the total expenses payable by us in connection with this offering, excluding the underwriting discount referred to above, will be approximately $325,000.

We have agreed, subject to certain conditions, limitations and exceptions, to provide the underwriter with a right to act as lead placement with respect to any private placement or registered direct offering that may be undertaken by us on or before April 3, 2023

Indemnification

We have agreed to indemnify the underwriter against certain liabilities, including liabilities under the Securities Act of 1933, as amended, or the Securities Act, and liabilities arising from breaches of representations and warranties contained in the underwriting agreement, or to contribute to payments that the underwriter may be required to make in respect of those liabilities.

Lock-up Agreements

We, and our officers and directors have agreed, subject to limited exceptions, for a period of 90 days after the date of the underwriting agreement, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any shares of common stock or any securities convertible into or exchangeable for our common stock either owned as of the date of the underwriting agreement or thereafter acquired without the prior written consent of the underwriter. The underwriter may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

Price Stabilization, Short Positions and Penalty Bids

In connection with the offering the underwriter may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- Over-allotment involves sales by the underwriter of shares in excess of the number of shares the underwriter is obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriter are not greater than the number of shares that it may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriter may close out any covered short position by either exercising its over-allotment option and/or purchasing shares in the open market.

- Syndicate covering transactions involve purchases of shares of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which it may purchase shares through the over-allotment option. If the underwriter sells more shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor the underwriter makes any representations that the underwriter will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

Listing and Transfer Agent

Our common stock is listed on Nasdaq and trades under the symbol "*ENSC*." The transfer agent of our common stock is Continental Stock Transfer & Trust Company. We do not plan on making an application to list the pre-funded warrants, Series A warrants or Series B warrants on Nasdaq, any national securities exchange or other nationally recognized trading system. Continental Stock Transfer & Trust Company will act as the registrar and transfer agent for the warrants.

Electronic Distribution

This prospectus in electronic format may be made available on websites or through other online services maintained by the underwriter, or by its affiliates. Other than this prospectus in electronic format, the information on the underwriter's website and any information contained in any other website maintained by the underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriter in its capacity as an underwriter, and should not be relied upon by investors.

Other

From time to time, the underwriter and/or its affiliates have provided, and may in the future provide, various investment banking and other financial services for us for which services they have received and, may in the future receive, customary fees. In the course of its businesses, the underwriter and its affiliates may actively trade our securities or loans for their own account or for the accounts of customers, and, accordingly, the underwriter and its affiliates may at any time hold long or short positions in such securities or loans. Except for services provided in connection with this offering and except as described below, the underwriter has not provided any investment banking or other financial services to us during the 180-day period preceding the date of this prospectus and we do not expect to retain the underwriter to perform any investment banking or other financial services for at least 90 days after the date of this prospectus. Lake Street acted as our exclusive placement agent for our 2021 Notes and 2022 Notes offerings. Lake Street received a placement agent fee of $400,000 in connection with the offering of the 2022 Notes.

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by Troutman Pepper Hamilton Sanders LLP. Lowenstein Sandler LLP, New York, New York, is acting as counsel for the underwriter in connection with this offering.

EXPERTS

Our consolidated financial statements as of and for the years ended December 31, 2021 and 2020, included in this registration statement/prospectus, have been audited by Mayer Hoffman McCann P.C., independent registered public accounting firm, as set forth in their report (which report includes an explanatory paragraph regarding the existence of substantial doubt about our ability to continue as a going concern), appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing, in giving said reports.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1, including exhibits, under the Securities Act of 1933, as amended, with respect to the securities offered by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our securities, you should refer to the registration statement and our exhibits.

In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public on a website maintained by the SEC located at www.sec.gov. We also maintain a website at www.ensyce.com. Through our website, we make available, free of charge, annual, quarterly and current reports, proxy statements and other information as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on, or that may be accessed through, our website is not part of, and is not incorporated into, this prospectus.

Financial Statements

ENSYSCE BIOSCIENCES, INC.
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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, except with respect to the impact of the reverse stock split discussed in Notes 2 and 12, as to which the date is November 16, 2022.

Ensysce Biosciences, Inc.
Consolidated Balance Sheets

	December 31,			
		2021		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; 1,233,148 and 788,437 shares issued at December 31, 2021 and December 31, 2020, respectively; 1,232,160 and 788,437 shares outstanding at December 31, 2021 and December 31, 2020, respectively		124		79
Additional paid-in capital		77,967,200		49,517,835
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):				

	2021		2020
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	$ (29.64)		$ 0.07
Weighted average common shares outstanding, basic	1,008,227		788,437
Net income (loss) per diluted share:			
Net income (loss) per share attributable to common stockholders, diluted	$ (29.64)		$ 0.07
Weighted average common shares outstanding, diluted	1,008,227		825,370

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)	11,973,258	**$ 300**	**$ 49,338,935**	**$ (56,015,486)**	**$ -**	**$ (6,676,251)**
Retroactive application of recapitalization	(11,184,821)	(220)	220	-	-	-
Balance on December 31, 2019, effect of reverse recapitalization (Note 2)	788,437	**$ 80**	**$ 49,339,155**	**$ (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	788,437	**$ 80**	**$ 49,517,834**	**$ (55,958,716)**	**$ (217,625)**	**$ (6,658,427)**
Exercise of stock options	14,241	1	262,861	-	-	262,862
Settlement of convertible notes in business combination	67,899	7	5,696,696	-	-	5,696,703
Conversion of convertible notes	19,369	2	2,247,613	-	-	2,247,615
Issuance of common stock for business combination, net of transaction costs	342,214	34	7,695,230	-	-	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	1,232,160	**$ 124**	**$ 77,967,200**	**$ (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 outstanding common 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.

Ensysce Biosciences, Inc.
Notes to the Consolidated Financial Statements

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.

Reverse Stock Split

In October 2022, the Company completed a 1-for-20 reverse split of its outstanding common stock. All references in these consolidated financial statements to shares and per share amounts in all periods have been retroactively restated to reflect the split (see Note 12).

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 55,306 warrants with a five-year term to purchase common stock of Ensysce at an exercise price of $200.20 per share (Notes 3 and 8), subject to a down round feature that would adjust the exercise price if other shares are issued below $200.20 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 $3.4 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	December 31, 2020
Numerator:		
Net income (loss) attributable to common stockholders	$ (29,886,851)	$ 56,770
Denominator:		
Weighted average shares outstanding, basic	1,008,227	788,437
Weighted average dilutive stock options	-	36,933
Weighted average shares outstanding, diluted	1,008,227	825,370
Net income (loss) per share attributable to common stockholders, basic	$ (29.64)	$ 0.07
Net income (loss) per share attributable to common stockholders, diluted	$ (29.64)	$ 0.07

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	December 31, 2020
Stock options	224,915	182,015
Warrants	513,688	988
Total	738,603	183,003

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	$	-

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 $230.00 per share to $200.00 per 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 25,000 shares of common stock with a five-year term and an exercise price of $125.60 each, 2,500 shares of common stock each, and 10,000 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.

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 $5.00 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	756	$ -
2018 Convertible Notes	3,500,000	901,466	4,401,466	62,992	-
2020 Convertible Notes	700,000	64,438	764,438	3,850	-
2021 Convertible Note	50,000	2,082	52,082	301	-
Total	$ 4,350,000	$ 999,137	$ 5,349,137	67,899	$ -

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 $5.9 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 $117.40, 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 12,777 shares of common stock in repayment of $1.5 million, the shares issued at the stated conversion price of $117.40. 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 $90.00 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 $117.40 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 $90.00. 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) $117.40 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 $15.60 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 $1/18^{th}$ 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:

- 802,679 shares of common stock were issued to holders of Former Ensysce common stock.

- 310,963 shares of common stock outstanding were assumed by the Company.

- 67,899 shares of common stock were issued in settlement of $5.8 million of convertible debt.
- 988 shares of restricted common stock were issued in exchange for previously outstanding warrants to purchase Former Ensysce common stock.
- 25,000 shares of common stock were issued in settlement of a termination agreement with a strategic advisor dated January 2021.
- 6,250 shares of common stock were issued in settlement of deferred underwriting costs.

Warrants

In February 2013, the Company issued 659 warrants to purchase common stock, with a ten-year life and an exercise price of $124.60 per share. In August 2019, in connection with the issuance of convertible debt, the Company issued 329 warrants to purchase common stock, with a ten-year life and an exercise price of $60.80. As of December 31, 2020, the warrants remained outstanding. On June 30, 2021, the Company issued 988 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)	945,063	$ 200.00 - 230.00	LACQ warrants	Equity
(b)	55,306	$ 90.00	Share subscription facility	Equity
(c)	18,058	$ 152.60	Convertible note	Liability
(d)	36,116	$ 152.60	Convertible note	Liability
	1,054,543			

a) On June 30, 2021, as a result of the Closing, the Company assumed a total of 945,063 warrants previously issued by LACQ. The warrants provide holders the right to purchase common stock at a strike price of between $200.00 and $230.00 per share and expire June 30, 2026, five years following the completion of the Business Combination. A total of 500,000 of the outstanding warrants are public warrants which trade on the OTC Pink Open Market under the ticker symbol ENSCW. The remaining 445,063 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 25,000 warrants issued on June 30, 2021 from $230.00 to $200.00, 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 55,306 warrants to purchase common stock pursuant to the share subscription facility. The warrants have a three-year life and an exercise price of $200.20 per share. The grant date fair value of the warrants, based on the $289.80 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 $90.00 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 18,058 warrants in connection with the issuance of the 2021 Notes. The warrants were immediately exercisable with an exercise price of $152.60 (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 36,116 warrants in connection with the issuance of the 2021 Notes. The warrants were immediately exercisable with an exercise price of $152.60 (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	$ 289.80	289.80	$ 89.80	$ 94.00	$ 45.00	$ 94.00
Exercise price	$ 200.00 - 230.00	200.20	$ 152.60	$ 152.60	$ 152.60	$ 152.60
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 221,191 options outstanding under Former Ensysce stock plans and reserves for issuance an additional50,000 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	**2020**
Legacy Plans	-	27,154
2016 Plan	-	201,706
2019 Directors Plan	-	7,573
2021 Omnibus Plan	222,191	-
Total options outstanding	222,191	236,433

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 of6,585 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 $67.00 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	236,433	$ 45.60	6.80	$ 1,817,383
Granted	-	-		-
Exercised	(12,242)	18.20		472,453
Expired / Forfeited	-	-		-
Outstanding at December 31, 2021	222,191	48.00	6.00	10,207,306
Exercisable at December 31, 2021	216,899	47.60	5.90	10,055,725
Vested and expected to vest	222,191	48.00	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	$ 51.60
Exercise price	$ 67.00
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 $44.00. 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	222,191
Stock options available for future grant under 2021 Omnibus Incentive Plan	50,000
Warrants outstanding	1,054,543
Total shares of common stock reserved for future issuance	1,326,734

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 150,000 shares available for future grant. Following this approval, the Company has granted a total of 99,300 stock options and 46,367 restricted stock units under the Plan to employees and consultants in 2022.

In the first quarter of 2022, the Company has issued 235,428 shares of common stock in repayment of $6.4 million in monthly redemptions of the 2021 Notes, as discussed in Note 7.

On October 28, 2022, the Company completed a 1-for-20 reverse split of its outstanding common stock. All references in these consolidated financial statements to shares and per share amounts have been retroactively restated to reflect the split.

ENSYSCE BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		

Cash and cash equivalents	$ 4,503,081	$ 12,264,736
Unbilled receivable	140,813	441,721
Right-of-use asset	35,313	24,721
Prepaid expenses and other current assets	2,983,071	2,931,415
Total current assets	7,662,278	15,662,593
Property and equipment, net	-	-
Other assets	627,550	754,756
Total assets	$ 8,289,828	$ 16,417,349
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,285,514	$ 301,104
Accrued expenses and other liabilities	2,236,273	3,407,533
Payable to related parties	800,000	-
Lease liability	35,403	24,874
Notes payable and accrued interest ($7,199,135 and $12,358,886 at fair value at September 30, 2022 and December 31, 2021, respectively)	7,552,774	12,748,155
Total current liabilities	11,909,964	16,481,666
Long-term liabilities:		
Notes payable, net of current portion (at fair value)	1,386,967	4,440,951
Other long-term liabilities	1,414,829	3,652,790
Total long-term liabilities	2,801,796	8,093,741
Total liabilities	$ 14,711,760	$ 24,575,407
Commitments and contingencies (Note 6)		
Stockholders' deficit		
Preferred stock, $0.0001 par value, 1,500,000 shares authorized, no shares issued and outstanding at September 30, 2022 (unaudited) and December 31, 2021	-	-
Common stock, $0.0001 par value, 250,000,000 and 150,000,000 shares authorized at September 30, 2022 and December 31, 2021; 2,208,446 and 1,233,148 shares issued at September 30, 2022 (unaudited) and December 31, 2021, respectively; 2,207,458 and 1,232,160 shares outstanding at September 30, 2022 (unaudited) and December 31, 2021, respectively	221	124
Additional paid-in capital	99,314,436	77,967,200
Accumulated deficit	(105,409,155)	(85,845,567)
Total Ensysce Biosciences, Inc. stockholders' deficit	(6,094,498)	(7,878,243)
Noncontrolling interests in stockholders' deficit	(327,434)	(279,815)
Total stockholders' deficit	(6,421,932)	(8,158,058)
Total liabilities and stockholders' deficit	$ 8,289,828	$ 16,417,349

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

ENSYSCE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Federal grants	$ 279,351	$ 1,200,816	$ 1,089,920	$ 1,895,907
Operating expenses:				
Research and development	4,756,096	1,714,635	13,393,948	2,502,232
General and administrative	1,686,580	16,372,976	5,717,281	17,257,361
Total operating expenses	6,442,676	18,087,611	19,111,229	19,759,593
Loss from operations	(6,163,325)	(16,886,795)	(18,021,309)	(17,863,686)
Other income (expense):				
Issuance costs for convertible notes	(1,118,721)	(500,158)	(1,118,721)	(500,158)
Change in fair value of derivative liabilities	-	-	-	673,314
Loss on issuance of convertible notes	(3,609,944)	-	(3,609,944)	-
Change in fair value of convertible notes	3,491,513	1,071,099	6,169,929	1,071,099
Issuance of liability classified warrants	(3,737,371)	(1,325,804)	(3,737,371)	(1,325,804)
Change in fair value of liability classified warrants	2,683,340	405,086	5,626,130	405,086
Loss on debt conversions	(1,404,877)	-	(4,000,155)	-
Interest expense	(4,859)	(24,660)	(57,662)	(1,282,820)
Loss on extinguishment of debt	-	-	-	(347,566)
Other income and expense, net	8,679	61,758	19,494	61,758
Total other income (expense), net	(3,692,240)	(312,679)	(708,300)	(1,245,091)
Net loss	$ (9,855,565)	$ (17,199,474)	$ (18,729,609)	$ (19,108,777)
Net loss attributable to noncontrolling interests	(21,492)	(35,948)	(47,619)	(61,976)
Deemed dividend related to warrants down round provision	63,539	-	881,598	-
Net loss attributable to common stockholders	$ (9,897,612)	$ (17,163,526)	$ (19,563,588)	$ (19,046,801)
Net loss per share:				
Net loss per share attributable to common stockholders, basic and diluted	$ (5.13)	$ (14.15)	$ (11.74)	$ (20.31)
Weighted average common shares outstanding, basic and diluted	1,928,727	1,212,791	1,666,253	937,764

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

ENSYSCE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)

	Stockholders' Equity (Deficit)					
	Common Stock		Additional			
	Number of Shares	Amount	Paid - In Capital	Accumulated Deficit	Noncontrolling interests	Total
Balance on June 30, 2021	**1,212,791**	**$ 122**	**$ 63,252,814**	**$ (57,841,991)**	**$ (243,653)**	**$ 5,167,292**
Stock-based compensation	-	-	24,833	-	-	24,833
Issuance of warrants	-	-	11,565,472	-	-	11,565,472
Warrants modification	-	-	56,590	-	-	56,590
Net loss	-	-	-	(17,163,526)	(35,948)	(17,199,474)
Balance on September 30, 2021	**1,212,791**	**$ 122**	**$ 74,899,709**	**$ (75,005,517)**	**$ (279,601)**	**$ (385,287)**
Balance on June 30, 2022	**1,776,520**	**$ 178**	**$ 95,019,729**	**$ (95,511,543)**	**$ (305,942)**	**$ (797,578)**
Conversion of convertible notes	428,438	43	4,074,020	-	-	4,074,063
Stock-based compensation	-	-	157,148	-	-	157,148
Settlement of restricted stock units	2,500	-	-	-	-	-
Deemed dividend related to warrants down round provision	-	-	63,539	(63,539)	-	-
Net loss	-	-	-	(9,834,073)	(21,492)	(9,855,565)
Balance on September 30, 2022	**2,207,458**	**$ 221**	**$ 99,314,436**	**$ (105,409,155)**	**$ (327,434)**	**$ (6,421,932)**

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

ENSYSCE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)

	Stockholders' Equity (Deficit)					
	Common Stock		Additional			
	Number of Shares	Amount	Paid-In Capital	Accumulated Deficit	Noncontrolling interests	Total
Balance on December 31, 2020	**11,973,258**	**$ 300**	**$ 49,517,614**	**$ (55,958,716)**	**$ (217,625)**	**$ (6,658,427)**
Retroactive application of recapitalization	(11,184,821)	(220)	220	-	-	-
Balance on December 31, 2020, effect of reverse recapitalization	**788,437**	**80**	**49,517,834**	**(55,958,716)**	**(217,625)**	**(6,658,427)**
Exercise of stock options	14,241	1	262,861	-	-	262,862
Settlement of convertible notes	67,899	7	5,696,696	-	-	5,696,703
Issuance of common stock for business combination, net of transaction costs	342,214	34	7,695,230	-	-	7,695,264
Stock-based compensation	-	-	105,026	-	-	105,026
Issuance of warrants	-	-	11,565,472	-	-	11,565,472
Warrants modification	-	-	56,590	-	-	56,590
Net loss	-	-	-	(19,046,801)	(61,976)	(19,108,777)
Balance on September 30, 2021	**1,212,791**	**$ 122**	**$ 74,899,709**	**$ (75,005,517)**	**$ (279,601)**	**$ (385,287)**
Balance on December 31, 2021	**1,232,160**	**$ 124**	**$ 77,967,200**	**$ (85,845,567)**	**$ (279,815)**	**$ (8,158,058)**
Consultant compensation	2,507	-	54,250	-	-	54,250
Conversions of convertible notes	937,924	93	17,868,004	-	-	17,868,097
Settlement of restricted stock units	34,867	4	(4)	-	-	-
Stock-based compensation	-	-	2,543,388	-	-	2,543,388
Deemed dividend related to warrants down round provision	-	-	881,598	(881,598)	-	-
Net loss	-	-	-	(18,681,990)	(47,619)	(18,729,609)
Balance on September 30, 2022	**2,207,458**	**$ 221**	**$ 99,314,436**	**$ (105,409,155)**	**$ (327,434)**	**$ (6,421,932)**

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

ENSYSCE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (18,729,609)	$ (19,108,777)

Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	-	151
Gain on sale of asset	(4,500)	-
Accrued interest	57,536	336,851
Accretion of discounts on promissory notes	-	945,969
Change in fair value of derivative liabilities	-	(673,314)
Change in fair value of liability classified warrants	(5,626,130)	-
Loss on issuance of convertible notes	3,609,944	-
Change in fair value of convertible notes	(6,169,929)	(1,071,099)
Loss on extinguishment of debt	-	347,566
Stock-based compensation	855,160	105,026
Issuance of warrants for share subscription facility	-	11,565,472
Issuance of liability classified warrants	3,737,371	620,718
Issuance costs for convertible notes	946,085	800,158
Commitment fee for share subscription facility	-	1,124,292
Warrant modification	-	56,590
Lease cost	(63)	(1,838)
Loss on debt conversions	4,000,155	-
Changes in operating assets and liabilities:		
Unbilled receivable	300,908	(86,867)
Prepaid expenses and other assets	475,499	(683,492)
Accounts payable	984,410	(1,252,740)
Accrued expenses and other liabilities	971,344	2,500,970
Net cash used in operating activities	(14,591,819)	(4,474,364)
Cash flows from investing activities:		
Proceeds from sale of asset	4,500	-
Net cash provided by investing activities	4,500	-
Cash flows from financing activities:		
Proceeds from issuance of convertible notes, net	7,533,915	4,549,842
Proceeds from issuance of promissory notes to related parties	-	350,000
Proceeds from exercise of stock options	-	262,862
Repayment of promissory notes	-	(467,774)
Repayments of convertible notes	(265,812)	-
Proceeds from issuance of common stock for business combination, net of transaction costs	-	6,626,312
Repayment of financed insurance premiums	(442,439)	(195,420)
Net cash (used in) provided by financing activities	6,825,664	11,125,822
Increase in cash and cash equivalents	(7,761,655)	6,651,458
Cash and cash equivalents beginning of period	12,264,736	194,214
Cash and cash equivalents end of period	$ 4,503,081	$ 6,845,672
Supplemental cash flow information:		
Income tax payments	$ 1,600	$ 1,600
Supplemental disclosure of non-cash investing and financing activities:		
Stock-based compensation	$ 1,742,478	$ -
Conversions of convertible notes and accrued interest into common stock	$ 13,879,535	$ 5,696,703
Payable to related parties	$ 800,000	$ -
Net assets acquired in business combination	$ -	$ 1,068,950
Financed insurance premiums	$ 399,949	$ 867,300
Share subscription facility transaction costs	$ -	$ 12,689,764
Deemed dividend related to warrants down round provision	$ 881,598	$ -

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

ENSYSCE BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1 – ORGANIZATION AND PRINCIPAL ACTIVITIES

Ensysce Biosciences, Inc. (“Ensysce”), along with its subsidiary, EBIR, Inc. (“EBIR”, formerly Covistat, Inc.) and its wholly-owned subsidiaries EBI Operating, Inc. and EBI OpCo, Inc. (collectively, the “Company”), is a clinical-stage biotech company using its two novel proprietary technology platforms to develop safer prescription drugs. The primary focus of the Company is developing abuse and overdose resistant pain drugs, with a clinical stage program for the abuse resistant, TAAP (Trypsin Activated Abuse Protection) opioid product candidate, PF614. In addition, the Company is developing its MPAR™ (Multi-Pill Abuse Resistance) technology for overdose protection which will be applied to the PF614 program. The Company has also commenced development work applying its TAAP and MPAR™ technology to a methadone prodrug for use in the treatment of Opioid Use Disorder (OUD).

On January 31, 2021, LACQ entered into the Merger Agreement with Former Ensysce and 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”). 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 outstanding common 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 began trading 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. In August 2022, Covistat was renamed EBIR, Inc. Ensysce is a 79.2% stockholder in EBIR, with 19.8% and 1.0% of the shares held by certain key personnel of the Company and an unrelated party, respectively. EBIR's emphasis is now on developing one or more compounds utilized in Ensysce's overdose protection program for the treatment of respiratory diseases.

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 GAAP and pursuant to the rules and regulations of the 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.

In the opinion of management, all adjustments considered necessary for a fair presentation have been included in the consolidated financial statements. Operating results for the three and nine months ended September 30, 2022, are not necessarily indicative of the results that may be expected for the year ending December 31, 2022. The interim unaudited consolidated financial statements have been prepared under the presumption that users of the interim financial information have either read or have access to the audited consolidated financial statements for the fiscal year ended December 31, 2021, which may be found in the Company's Form 10-K filed with the SEC on March 31, 2022.

Reverse Stock Split

In October 2022, the Company completed a 1-for-20 reverse split of its outstanding common stock. All references in these consolidated financial statements to shares and per share amounts in all periods have been retroactively restated to reflect the split (see Note 11).

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 financial statements reflect the historical operations of Ensysce.

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 $105.4 million at September 30, 2022. There is no assurance that profitable operations will ever be achieved, and, if achieved, could 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 the GEM Agreement. 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 controls 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, 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 55,306 warrants with a five-year term to purchase common stock of Ensysce at an exercise price of $200.20 per share (Note 8). The Company is required to pay a commitment fee to the investor of $1.2 million with $0.8 million due on the first anniversary of the public listing date and $0.4 million due on the 18-month anniversary of the public listing date. The first $0.8 million of the commitment fee was paid in July 2022 in common stock of the Company (Note 10) and the remaining $0.4 million due in January 2023 may 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") (See Note 7 for additional information). In July and August 2022, the Company received funding under a $8.48 million convertible note financing agreement with the same institutional investors (the "2022 Notes") (Note 7). The agreements limit the Company's ability to execute certain debt and equity financings, including under the GEM Agreement, while the convertible notes are outstanding. Without the availability of proceeds through the GEM Agreement, 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, warrants, options to purchase the Company's common stock, and the 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. No depreciation expense was recognized for the three and nine months ended September 30, 2022. Depreciation expense of $50 and $151 was recognized for the three and nine months ended September 30, 2021. 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 three and nine months ended September 30, 2022 and 2021.

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.

Fair Value Measurement

ASC 820, *Fair Value Measurements*, ("ASC 820") provides guidance on the development and disclosure of fair value measurements. Pursuant to ASC 820, 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 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 September 30, 2022 and December 31, 2021, 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

In 2021 the Company issued convertible notes with a face value of $15.9 million. 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.

2022 Notes

In July 2022 the Company issued convertible notes with a face value of $8.5 million. The 2022 Notes are accounted for under ASC 480 – *Distinguishing Liabilities from Equity,* due to share settlement features contained within the notes. As a result, the 2022 Notes are recorded as liabilities at fair value at the balance sheet date with changes in the fair value of the notes recognized in other income (expense) for each reporting period. The fair value estimate of the 2022 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. Refer to Note 7 for details of the terms and conditions of the 2022 Notes.

Warrants

In 2021 the Company issued liability classified warrants in connection with the issuance of the 2021 Notes. In 2022 the Company issued liability classified warrants in connection with the issuance of the 2022 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 for details of the warrants.

The following tables present assets and liabilities measured and recorded at fair value on the Company's consolidated balance sheet as of September 30, 2022 and December 31, 2021.

	September 30, 2022			
	Total	Level 1	Level 2	Level 3
Fair value of convertible notes	$ 8,586,102	$ -	$ -	$ 8,586,102
Liability classified warrants	1,414,829	-	-	1,414,829
Total	$ 10,000,931	$ -	$ -	$ 10,000,931

	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

The following table summarizes the change in fair value of the Company's Level 3 assets and liabilities:

	Total	Convertible notes	Liability classified warrants
Fair value, December 31, 2021	$ 20,103,425	$ 16,799,837	$ 3,303,588
Additions, net	12,217,371	8,480,000	3,737,371
Conversions	(14,133,750)	(14,133,750)	-
Change in fair value	(8,186,115)	(2,559,985)	(5,626,130)
Fair value, September 30, 2022	$ 10,000,931	$ 8,586,102	$ 1,414,829

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 June 2022, the Company received a Notice of Award for an additional $2.8 million of funding in year 4 under the MPAR Grant from July 1, 2022 through June 30, 2023. This brings total funding under this grant to approximately $10.8 million.

In September 2019, the NIH/National Institute on Drug Abuse awarded the Company a research and development grant related to the development of its TAAP/MPAR™ abuse deterrent technology for Opioid Use Disorder ("OUD") (the "OUD Grant"). The total approved budget was approximately $5.4 million and the current grant period ends in August 2023.

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 reimbursable 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:

	Three Months Ended		Nine months ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
MPAR	$ 206,290	$ 1,119,312	$ 710,761	$ 1,246,424
OUD	73,061	81,504	379,159	649,483
Total	$ 279,351	$ 1,200,816	$ 1,089,920	$ 1,895,907

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.

Immaterial Correction of an Error Adjusted in Prior Quarter

In August 2022, the Company concluded that due to an error in the measurement of the unbilled receivable and the associated grant revenue as of December 31, 2021, and March 31, 2022, the June 30, 2022, balance sheet would be adjusted. The change resulted in a decrease in the balance of the unbilled receivable of $214,308 as of June 30, 2022 and a corresponding increase in general and administrative expense presented in the consolidated statement of operations for the three months ended June 30, 2022.

The Company, in consultation with the Audit Committee of the Board of Directors, evaluated the effect of these adjustments on the Company's consolidated financial statements under ASC 250, Accounting Changes and Error Corrections and Staff Accounting Bulletin No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements and determined it was not necessary to recall its previously issued consolidated financial statements as the errors did not materially misstate any previously issued consolidated financial statements and the correction of the error in the current fiscal year is also not material. The Company looked at both quantitative and qualitative characteristics of the required corrections in making the determination.

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 three and nine months ended September 30, 2022 and 2021, stock-based compensation costs are recorded in general and administrative expenses and research and development 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 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net loss attributable to common stockholders	$ (9,897,612)	$ (17,163,526)	$ (19,563,588)	$ (19,046,801)
Denominator:				
Weighted average shares outstanding, basic and diluted	1,928,727	1,212,791	1,666,253	937,764
Net loss per share attributable to common stockholders, basic and diluted	$ (5.13)	$ (14.15)	$ (11.74)	$ (20.31)

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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options	350,995	222,203	328,538	225,833
Warrants	1,421,306	1,000,953	1,177,247	335,531
Total	1,772,301	1,223,156	1,505,785	561,364

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. On January 1, 2022, the Company adopted ASU 2019-12 and the adoption did not have a significant impact 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.

In May 2021, the FASB issued ASU No. 2021-04, Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (A Consensus of the FASB Emerging Issues Task Force (the "EITF")) – to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The guidance in the ASU requires the issuer to treat a modification of an equity-classified warrant that does not cause the warrant to become liability-classified as an exchange of the original warrant for a new warrant. This guidance applies whether the modification is structured as an amendment to the terms and conditions of the warrant or as termination of the original warrant and issuance of a new warrant. Under the amendments, an issuer should measure the effect of a modification as the difference between the fair value of the modified warrant and the fair value of that warrant immediately before modification. The EITF concluded that the recognition of the modification depends on the nature of the transaction in which a warrant is modified. If there is more than one element in a transaction (for example, if the modification involves both a debt modification and an equity issuance), then the guidance requires the issuer to allocate the effect of the option modification to each element. On January 1, 2022, the Company adopted ASU 2021-04 and the adoption did not have a significant impact on the consolidated financial statements.

NOTE 4 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	September 30, 2022	December 31, 2021
Prepaid research and development	$ 2,323,473	$ 2,124,008
Prepaid insurance	550,634	733,234
Other prepaid expenses	108,964	74,173
Total prepaid expenses and other current assets	$ 2,983,071	$ 2,931,415

NOTE 5 – ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consisted of the following:

	September 30, 2022	December 31, 2021
Share subscription facility commitment fees	$ 400,000	$ 800,000
Accrued research and development	1,186,498	388,997
Bonus accrual	297,224	610,000
Professional fees	203,034	138,086
Accrued scientific advisory board fees	60,032	60,032
Consultant stock compensation expenses	-	1,342,479
Other accrued liabilities	89,485	67,939
Total accrued expenses and other liabilities	$ 2,236,273	$ 3,407,533

Other long-term liabilities consisted of the following:

	September 30, 2022	December 31, 2021
Share subscription facility commitment fees	$ -	$ 349,202
Liability classified warrants	1,414,829	3,303,588
Total other long-term liabilities	$ 1,414,829	$ 3,652,790

NOTE 6 – COMMITMENTS AND CONTINGENCIES

Purchase Commitments

As of September 30, 2022, the Company's commitments included an estimated $25.7 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 September 30, 2022 and December 31, 2021, 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.

Lease

In August 2020, the Company entered into an agreement to lease office space. The original lease commencement date was October 1, 2020 and was subsequently amended to

extend the term of the lease through October 31, 2023 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 September 30, 2022, the future lease payments totaled $35,403.

The Company recognized total rent expense of $7,939 and $23,606 in the three and nine months ended September 30, 2022, and $11,781 and $36,058 in the three and nine months ended September 30, 2021.

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 25,000 shares of common stock with a five-year term and an exercise price of $125.60 each, 2,500 shares of common stock each, and 10,000 restricted stock units each. The restricted stock units vested over one year with 50% of the vesting contingent upon certain market conditions. These equity awards were contingent upon shareholder approval of an amended and restated 2021 Omnibus Plan at a special shareholder meeting in January 2022, at which time the warrants were replaced by non-qualified stock options with similar terms. As the original 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 $1,342,479 to reflect the estimated value of services received during the period. On February 14, 2022, the equity awards were granted, and the Company reclassified the outstanding liability to stockholders' equity (See Note 9 for additional details of the Company's stock-based compensation).

NOTE 7 – NOTES PAYABLE

The following table provides a summary of the Company's outstanding debt as of September 30, 2022:

	Principal balance	Accrued interest	Fair Value Adjustment	Net debt balance
2021 Notes	$ 379,695	$ 11,006	$ -	$ 390,701
2022 Notes	8,126,667	93,559	(24,825)	8,195,401
Financed Insurance	348,780	4,859	-	353,639
Total	$ 8,855,142	$ 109,424	$ (24,825)	$ 8,939,741

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

	Three months ended		Nine months ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
Stated interest accrual	$ 4,859	$ 24,660	$ 6,864	$ 251,857
Debt discount amortization	-	-	-	945,969
Total	$ 4,859	$ 24,660	$ 6,864	$ 1,197,826

2021 Notes

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

The proceeds of the 2021 Notes 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 $5.9 million. The Company recorded total issuance costs of $1.9 million representing investment banking and legal fees of $1.0 million and original issue discounts of $0.9 million. After multiple conversions (at original contract terms and at amended reduced conversion prices) since issuance, the Company reflected the remaining balance due as of September 30, 2022 and recognized a change in fair value of convertible notes of $45,329 (loss) for the three-month period then ended and a change in fair value of convertible notes of $2.7 million (gain) for the nine-month period ended September 30, 2022 primarily due to reductions in the Company's stock price. The September 30, 2022 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 amount of interest expense after consideration of the conversions would be $39,847 and $0.2 million for the three- and nine-month periods ended September 30, 2022, respectively.

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 $117.40, 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.

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) $117.40 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 $15.60 and the Company has been in compliance with customary requirements under the agreement, unless

waived in writing by the holder. If the applicable conversion price is less than $15.60 at the time of the Monthly Redemption Date the Company will be required to fund the difference in cash. During the period ended September 30, 2022, the Company paid $265,812 to fund such differences in cash (reducing the outstanding principal balance of the 2021 Notes).

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).

The following table provides a summary of the Company's 2021 note conversions during the nine-month period ending September 30, 2022:

Three Months Ended	Shares	Weighted Average Conversion Price	Conversion Value
March 31, 2022	235,428	$ 27.07	$ 6,372,700
June 30, 2022	274,058	$ 17.61	4,826,053
September 30, 2022	339,854	$ 6.84	2,323,081
Total	849,340		$ 13,521,834

On August 8, 2022, the parties agreed to modify the conversion price of the remaining 2021 Notes from $15.60 to $7.00 until October 1, 2022, with any remaining balance payable in cash on October 10, 2022. On September 20, 2022, the parties agreed to modify the conversion price of the remaining 2021 notes from $7.00 to $4.60 for the period from September 20, 2022 until September 30, 2022. The Company recorded an inducement expense equal to the excess fair value of the consideration transferred (utilizing the number of shares transferred multiplied by the average of the high/low price on the conversion date) above the securities that would have been issued under the original conversion terms. The total loss on debt conversions was $1.4 million and $4.0 million, for the three- and nine-month periods ended September 30, 2022 and is reflected in other income (expense), net. Included in the loss on debt conversions was $1.0 million related to the inducement expense for the three- and nine-month periods ended September 30, 2022, The remaining 2021 Notes became due and payable on October 10, 2022, at which time they were satisfied with cash (refer to Note 11).

2022 Notes

On June 30, 2022, the Company entered into an $8.0 million convertible financing agreement with institutional investors. The agreement provided for two closings, each for notes payable of $4.24 million (resulting in gross cash proceeds of $4.0 million). Funds were received for the first closing on July 1, 2022 and for the second closing on August 9, 2022.

On the issuance date, the Company assessed the probability of the potential settlement scenarios under the terms of the 2022 Notes and determined that the predominant settlement feature of the 2022 Notes was the redemption feature into shares of the Company's common stock issuable at the lower of the conversion price or 92% of the average of the three lowest VWAPs in the 10 trading days immediately preceding the redemption date. As the predominant settlement feature of the 2022 Notes is to settle a fixed monetary amount into a variable number of shares, the 2022 Notes fell within the scope of ASC 480. Accordingly, the Company determined that the 2022 Notes should be recorded at estimated fair value on its issuance date and adjusted to its estimated fair value as of each reporting date with the change in estimated fair value recorded as a component other income (expense) in the Company's consolidated statements of operations.

The Company recorded the 2022 Notes at an initial fair value of $12.06 million which included a loss upon issuance of $3.6 million. The loss upon issuance was due to the current share price at issuance exceeding the conversion price. Additionally, the Company recorded issuance costs of $1.1 million representing a 6% original issue discount of $0.5 million, $0.6 million of legal and investment banking fees, which are included in other income (expense) on the consolidated statement of operations. After an initial conversion since issuance, the Company reflected the remaining balance due as of September 30, 2022 at fair value and recognized a change in fair value of convertible notes of $3.5 million (gain) for the three and nine-month period then ended September 30, 2022 primarily due to reductions in the Company's stock price.

The September 30, 2022 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 amount of interest expense after consideration of the conversions would be $0.1 million for the three- and nine-month periods ended September 30, 2022.

The 2022 Notes are convertible into common stock, at a per share conversion price equal to $10.90, a 10% premium to the average price of the common stock for the three trading days prior to the first closing. Under the Notes, commencing on September 29, 2022 and continuing monthly on the first day of each month beginning November 2, 2022, the Company is obligated to redeem one fifteenth (1/15th) of the original principal amount under the applicable Note, plus accrued but unpaid interest.The Company may elect to pay all or part of the redemption amount in cash with a premium of eight percent or in conversion 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) during the ten consecutive trading days ending on the trading day that is immediately prior to the applicable redemption date, but in no event may the Company pay the redemption amount in conversion shares of common stock unless the conversion price is at least equal to $2.006 and the Company has been in compliance with customary requirements under the agreement, unless waived in writing by the holder.

In connection with each of the first and second closings of the 2022 Notes the Company also issued warrants to purchase233,395 shares of the Company's common stock. The warrants have an exercise price of $14.17, a 30% premium to the conversion price, and are exercisable forfive years following issuance of the 2022 Notes. The issuance of these warrants required the Company to reduce the conversion price of the 2021 Notes and the exercise price of the outstanding warrants associated with the 2021 Notes to $15.60.

The proceeds of the 2022 Notes will be used for working capital purposes subject to certain customary restrictions are secured by the Company's rights to its patents and licenses. The Company is restricted from issuing certain additional debt or equity without the prior written consent of the holders for certain specified periods set forth in the 2022 Notes. If, at any time while the 2022 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).

The 2022 Notes mature on December 29, 2023 and February 7, 2024, for the first and second closings, respectively. The notes bear interest at a rate of 6% 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 following table provides a summary of the Company's 2022 Notes conversions during the nine-month period ending September 30, 2022:

Three Months Ended	Shares	Weighted Average Conversion Price	Conversion Value
September 30, 2022	88,584	$ 4.04	$ 357,701
Total	88,584		$ 357,701

Financed insurance premiums

During year ended December 31, 2021, the Company financed its directors' and officers' liability insurance in the amount of $0.9 million, of which the note was paid in full as of September 30, 2022. During the quarter ended September 30, 2022, the Company financed its directors' and officers' liability insurance in the amount of $ 0.4 million. The Company expensed $4,589 and $6,684 of interest for the three and nine months ended September 30, 2022, respectively.

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. In September 2022, the Company amended and restated its Certificate of Incorporation to authorize shares up to a total of 250,000,000 shares of common stock. As of September 30, 2022 and December 31, 2021, there were no shares of preferred stock issued and outstanding.

Common Stock

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

- 802,679 shares of common stock were issued to holders of Former Ensysce common stock.
- 310,963 shares of common stock outstanding were assumed by the Company.
- 67,899 shares of common stock were issued in settlement of $5.8 million of convertible debt.
- 988 shares of restricted common stock were issued in exchange for previously outstanding warrants to purchase Former Ensysce common stock.
- 25,000 shares of common stock were issued in settlement of a termination agreement with a strategic advisor dated January 2021.
- 6,250 shares of common stock were issued in settlement of deferred underwriting costs.

Warrants

On September 30, 2022, outstanding warrants to purchase shares of common stock are as follows:

Reference	Shares Underlying Outstanding Warrants	Exercise Price	Description	Classification
(a)	945,063	$ 200.00 - 230.00	LACQ warrants	Equity
(b)	55,306	$ 4.04	Share subscription facility	Equity
(c)	18,058	$ 15.60	2021 Notes	Liability
(d)	36,116	$ 15.60	2021 Notes	Liability
(e)	233,394	$ 14.17	2022 Notes	Liability
(f)	233,394	$ 14.17	2022 Notes	Liability
	1,521,331			

a) On June 30, 2021, as a result of the closing of the Business Combination, the Company assumed a total of 945,063 warrants previously issued by LACQ. The warrants provide holders the right to purchase common stock at a strike price of between $200.00 and $230.00 per share and expire June 30, 2026, five years following the completion of the Business Combination. A total of 500,000 of the outstanding warrants are public warrants which trade on the OTC Pink Open Market under the ticker symbol ENSCW. The remaining 445,063 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 exercise price of 25,000 warrants issued on June 30, 2021 from $230.00 to $200.00, resulting in an incremental increase in their fair value of $56,590, recognized in general and administrative expense.

b) On July 2, 2021, upon public listing of the Company's shares, the Company issued 55,306 warrants to purchase common stock pursuant to the share subscription facility. The warrants have a three-year life and an exercise price of $200.20 per share. The grant date fair value of the warrants, based on the $289.80 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, January 3, 2022, February 1, 2022, March 1, 2022, May 2, 2022,June 1, 2022, July 1, 2022, August 10, 2022, September 20, 2022 and September 29, 2022 the exercise price of the warrants adjusted to $90.00 per share, $56.60 per share, $31.60 per share, $19.20 per share, $18.80 per share, $9.20 per share, $8.00 per share, $7.00 per share, $4.60 per share and $4.00 for those conversion dates, respectively, 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 18,058 warrants in connection with the issuance of the 2021 Notes. The warrants were immediately exercisable with an exercise price of $152.60 (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. As a result of the issuance of the 2022 Notes in July of 2022, the exercise price of these warrants was adjusted down to $15.60. 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 in other income (expense).

d) On November 5, 2021, the Company issued 36,116 warrants in connection with the issuance of the 2021 Notes. The warrants were immediately exercisable with an exercise price of $152.60 (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. As a result of the issuance of the 2022 Notes in July of 2022, the exercise price of these warrants was adjusted down to $15.60. 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 in other income (expense).

e) On July 1, 2022, the Company issued 233,394 warrants in connection with the issuance of the 2022 Notes. The warrants were immediately exercisable with an exercise price of $14.17 (subject to downward revision protection in the event the Company makes certain issuance of common stock at prices below the conversion price) and expire on June 29, 2027.

f) On August 9, 2022, the Company issued 233,394 warrants in connection with the issuance of the 2022 Notes. The warrants were immediately exercisable with an exercise price of $14.17 (subject to downward revision protection in the event the Company makes certain issuance of common stock at prices below the conversion price) and expire on August 8, 2027.

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 7/2/21)	(b) Share subscription facility (remeasurement date varies)
Stock price	$ 289.80	$289.80	$ 4.80-85.80
Exercise price	$ 200.00-230.00	$200.20	$ 4.00-90.00
Expected term (years)	3.00	3.00	1.76-2.49
Volatility	110.0%	110.0%	108.2%-125.3%
Risk free rate	0.5%	0.5%	1.0%-4.2%

	(c) Liability classified warrants (grant date 9/24/21)	(c) Liability classified warrants (remeasured at 9/30/22)	(d) Liability classified warrants (grant date 11/5/21)	(d) Liability classified warrants (remeasured at 9/30/22)
Stock price	$ 89.80	$ 4.30	$ 45.00	$ 4.30
Exercise price	$ 152.60	$ 15.60	$ 152.60	$ 15.60
Expected term (years)	5.00	4.00	5.00	4.10
Volatility	94.1%	116.1%	94.1%	114.9%
Risk free rate	1.0%	4.1%	1.0%	4.1%

	(e) Liability classified warrants (grant date 7/1/22)	(e) Liability classified warrants (remeasured 9/30/22)	(f) Liability classified warrants (grant date 8/9/22)	(f) Liability classified warrants (remeasured 9/30/22)
Stock price	$ 11.40	$ 4.40	$ 10.60	$ 4.40
Exercise price	$ 14.20	$ 14.20	$ 14.20	$ 14.20
Expected term (years)	5.00	4.75	5.00	4.86
Volatility	98.9%	109.4%	102.8%	108.3%
Risk free rate	2.9%	4.1%	3.0%	4.1%

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 221,191 options outstanding under Former Ensysce stock plans and reserves for issuance an additional 50,000 shares for future awards under the 2021 Omnibus Plan. On January 26, 2022, the 2021 Omnibus Plan was amended and restated to include an additional 150,000 shares available for future grant and to provide for future annual increases. No further awards may be made under the Former Ensysce stock plans.

The Company recognized within general and administrative expense stock-based compensation expense of $128,357 and $731,126 for the three and nine months ended September 30, 2022, and $24,833 and $105,026 for the three and nine months ended September 30, 2021. During the three and nine months ended September 30, 2022, the Company recognized stock-based compensation expense of $28,791 and $124,034 within research and development. During the three and nine months ended September 30, 2021, there was no stock-based compensation allocated to research and development.

Option Activity

During the nine months ended September 30, 2022, the Company granted stock options to purchase an aggregate of114,550 shares of common stock to employees, consultants and members of the board of directors. The options vest over periods between zero and 4 years and have an exercise price of between $8.50 and $125.60 per share. There were no stock option grants in 2021.

The following table summarizes the Company's stock option activity during the nine months ended September 30, 2022:

	Options	Weighted average Exercise price	Weighted average Remaining contractual life	Intrinsic value
Outstanding at December 31, 2021	222,191	$ 48.00	6.00	$ 10,207,306
Granted	114,550	77.30	7.63	-
Exercised	-	-	-	-
Expired / Forfeited	(10,000)	21.40	-	-
Outstanding at September 30, 2022	326,741	59.13	6.57	-
Exercisable at September 30, 2022	284,014	62.03	6.15	-
Vested and expected to vest	326,741	59.13	6.57	-

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):

	Nine Months Ended September 30, 2022
Stock price	$ 8.60 - 34.00
Exercise price	$ 8.5-125.60
Expected stock price volatility	76.61 - 95.87%
Expected term (years)	5.19-10.00
Risk-free interest rate	1.52% - 3.14%
Expected dividend yield	0%

- *Expected stock-price volatility.* The expected volatility is derived from the historical volatilities of publicly traded companies within the Company's industry that the Company considers to be comparable to the Company's business over a period approximately equal to the expected term.
- *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 nine months ended September 30, 2022 was $19.24. There were no options granted during the nine months ended September 30, 2021.

As of September 30, 2022, the Company had an aggregate of $605,868 of unrecognized share-based compensation cost, which is expected to be recognized over the weighted average period of 1.42 years.

Restricted Stock Units

The following table summarizes the Company's restricted stock units activity during the nine months ended September 30, 2022:

	Restricted Stock Units	Weight average fair value
Outstanding at December 31, 2021	-	$ -
Granted	61,367	23.02
Released	(34,867)	26.25
Cancelled	(10,000)	-
Outstanding at September 30, 2022	16,500	10.63

The remaining awards outstanding are subject to time-based vesting conditions and are scheduled to vest by December 2023. The estimated fair value of each of the Company's was determined on the date of grant based on the closing price of the Company's common stock on the previous trading date.

Shares Reserved for Future Issuance

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

	September 30, 2022
Awards outstanding under the 2021 Omnibus Incentive Plan	343,241
Awards available for future grant under 2021 Omnibus Incentive Plan	44,095
2022 Notes outstanding	754,149
Warrants outstanding	1,521,331
Total shares of common stock reserved for future issuance	2,662,816

NOTE 10 - RELATED PARTIES

The Company paid cash compensation during the three and nine months ended September 30, 2021 of $3,584 and $43,898, respectively, to the Chief Executive Officer through a separate operating company with which the Chief Executive Officer is affiliated. There were no such payments in the three and nine months ended September 30, 2022. In July 2022, the Chief Executive Officer and a Board member transferred 46,062 shares of registered common stock to GYBL to settle $0.8 million of Company obligations related to the GEM Agreement (Note 2). In October 2022, 46,062 shares of unregistered and restricted common stock were subsequently issued by the Company to the related parties as reimbursement.

NOTE 11 - SUBSEQUENT EVENTS

On October 11, 2022, the Company paid $390,701 in cash to fulfill the remaining amounts outstanding under the 2021 Notes.

On October 28, 2022, the Company completed a 1-for-20 reverse split of its outstanding common stock. All references in these consolidated financial statements to shares and per share amounts in all periods have been retroactively restated to reflect the split.

In the fourth quarter of 2022, the Company issued 573,944 shares of common stock as a result of conversions of $2.1 million of principal and interest of the 2022 Notes.

Ensysce Biosciences, Inc.

5,274,261 Shares of Common Stock
Pre-Funded Warrants to Purchase up to 5,274,261 Shares of Common Stock
Series A Warrants to Purchase up to 5,274,261 Shares of Common Stock
Series B Warrants to Purchase up to 5,274,261 Shares of Common Stock

PROSPECTUS

Lake Street

, 2022

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following is a statement of estimated expenses payable by the registrant in connection with the offering described in this registration statement. All amounts are estimates except the SEC registration fee and FINRA filing fees.

SEC expenses	$	4,752.39
FINRA filing fees		6,968.75
Accounting fees and expenses		25,000.00
Legal fees and expenses		80,000.00
Miscellaneous		8,278.86
Total	$	125,000.00

Item 14. Indemnification of Directors and Officers.

Section 102(b)(7) of the Delaware General Corporation Law (the "*DGCL*") allows a corporation to provide in its certificate of incorporation that a director of the corporation will not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except where the director breached the duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. The registrant's third amended and restated certificate of incorporation provides for this limitation of liability.

Section 145 of the DGCL, provides, among other things, that a Delaware corporation may indemnify any person who was, is or is threatened to be made, party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was unlawful. A Delaware corporation may indemnify any persons who were or are a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit, provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests, provided further that no indemnification is permitted without judicial approval if the officer, director, employee or agent is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses (including attorneys' fees) which such officer or director has actually and reasonably incurred.

Section 145 further authorizes a corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or enterprise, against any liability asserted against such person and incurred by such person in any such capacity, or arising out of his or her status as such, whether or not the corporation would otherwise have the power to indemnify such person under Section 145.

The registrant's amended and restated bylaws provide that it must indemnify and advance expenses to its directors and officers to the full extent authorized by the DGCL.

The registrant intends to enter into indemnification agreements with each of its directors and executive officers. Such agreements may require the registrant, among other things, to advance expenses and otherwise indemnify its executive officers and directors against certain liabilities that may arise by reason of their status or service as executive officers or directors, to the fullest extent permitted by law.

The indemnification rights set forth above shall not be exclusive of any other right which an indemnified person may have or hereafter acquire under any statute, any provision of the registrant's third amended and restated certificate of incorporation, the registrant's amended and restated bylaws, agreement, vote of stockholders or

disinterested directors or otherwise. Notwithstanding the foregoing, the registrant shall not be obligated to indemnify a director or officer in respect of a proceeding (or part thereof) instituted by such director or officer, unless such proceeding (or part thereof) has been authorized by the board of directors pursuant to the applicable procedure outlined in the registrant's amended and restated bylaws.

Section 174 of the DGCL provides, among other things, that a director, who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption, may be held jointly and severally liable for such actions. A director who was either absent when the unlawful actions were approved or dissented at the time may avoid liability by causing his or her dissent to such actions to be entered in the books containing the minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

The registrant maintains and expects to maintain standard policies of insurance that provide coverage (1) to its directors and officers against loss rising from claims made by reason of breach of duty or other wrongful act and (2) to the registrant with respect to indemnification payments that the registrant may make to such directors and officers.

These provisions may discourage stockholders from bringing a lawsuit against the registrant's directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit the registrant and its stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent the registrant pays the costs of settlement and damage awards against officers and directors pursuant to these indemnification provisions.

The registrant believes that these provisions, the insurance and the indemnity agreements are necessary to attract and retain talented and experienced officers and directors.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of capital stock issued by us within the past three years. Also included is the consideration received by us for such shares and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed. Share and per share amounts reported in this Item 15 have not been retroactively restated to reflect the Reverse Split.

- On June 25, 2020, LACQ issued an aggregate of 1,000,001 private warrants exercisable for 1,000,001 shares of common stock to Hydra Management, LLC ("*Hydra*"), Matthews Lane Capital Partners LLC ("*MLCP*" and together with Hydra, the "*Sponsors*"), and its strategic investor, HG Vora Capital Management LLC ("*HG Vora*"), on behalf of one or more funds or accounts managed by it, in connection with their conversion of promissory notes covering $1,000,000 of loans to LACQ under an Expense Advancement Agreement, as amended, among LACQ, the Sponsors and HG Vora (the "*Expense Advancement Agreement*").

- On January 31, 2021, LACQ issued 566,288 warrants exercisable for up to 566,288 shares of common stock to Gateway Holdings Limited in exchange for previously outstanding loans under the Expense Advancement Agreement dated December 5, 2019 between LACQ and Gateway Holdings Limited, as amended (the "*GTWY Expense Advancement Agreement*").
- On June 7, 2021, LACQ entered into exchange agreements with each of the holders of (i) LACQ's warrants issued by LACQ to the Sponsors and HG Vora (the "*Private Placement Warrants*") and (ii) other private warrants held by the Sponsors, HG Vora, certain members of former LACQ management and unaffiliated parties. Pursuant to the exchange agreements, each of these holders exchanged their warrants for new private warrants. In connection with this exchange, an aggregate of 8,391,289 Private Placement Warrants and other private warrants were exchanged for new private warrants in a transaction exempt from registration under the Act pursuant to Section 3(a)(9) of the Act.
- On June 7, 2021, we issued 500,000 warrants exercisable for up to 500,000 shares of common stock to DelMorgan Group LLC (the "*DelMorgan*") under the terms of the Email Agreement, dated January 31, 2021, among us and DelMorgan, as amended by the First Amendment to the Email Agreement, dated June 7, 2021 (the "*Email Agreement*").
- On June 30, 2021, we issued warrants to the Sponsors and HG Vora to purchase 510,001 shares of common stock that are issuable upon exercise of 510,001 warrants in exchange for outstanding loans under the Expense Advancement Agreement.
- On June 30, 2021, we issued 1,106,108 warrants with a 36-month term to purchase 1,106,108 shares of our common stock at a strike price per share equal to $10.01, to GEM Yield Bahamas Limited ("*GYBL*").
- On June 30, 2021, we issued 125,000 shares of common stock to the underwriters in LACQ's initial public offering to satisfy deferred underwriting fees payable to such underwriters.
- On July 22, 2021, we entered into agreements with consultants to issue up to 1,500,000 shares of common stock in the form of non-transferable warrants with a five-year term to purchase 1,000,000 shares of common stock at a strike price per share equal to $6.28 and up to 500,000 shares of common stock based on certain service and market price conditions.
- On September 24, 2021, we entered into a Securities Purchase Agreement (the "*2021 SPA*") whereby we issued to the Selling Securityholders signatory thereto 2021 Notes in the aggregate principal amount of $15.9 million for an aggregate purchase price of $15 million in two closings under the 2021 SPA, the first closing occurring on September 24, 2021 and the second occurring on November 5, 2021. The 2021 Notes, subject to an original issue discount of six percent (6%), had a term of twenty-one months and accrued interest at the rate of 5.0% per annum. The 2021 Notes were initially convertible into the common stock, at a per share conversion price equal to $5.87, but the conversion price was subsequently reduced. In these transactions we also issued warrants to purchase 1,083,475 shares of the common stock in the aggregate at an exercise price per share of $7.63, which was subsequently reduced to $0.78. We have registered with the SEC the resale of the shares of common stock issuable upon conversion of the Investor Notes as well as the shares of common stock issuable upon the exercise of the warrants.
- On February 18, 2022, we issued 50,000 shares of common stock to MZHCI, LLC in connection with our execution of 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. 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 June 30, 2022, we entered into a securities purchase agreement (the "*2022 SPA*") whereby we issued to the Selling Securityholders signatory thereto secured convertible promissory notes (the "*2022 Notes*") in the aggregate principal amount of $8.48 million for an aggregate purchase price of $8.0 million in two closings under the 2022 SPA, the first closing occurring on July 1, 2022 and the second occurring on August 8, 2022. The 2022 Notes, subject to an original issue discount of six percent (6%), have a term of eighteen months and accrue interest at the rate of 6.0% per annum. The 2022 Notes are convertible into the common stock, at a per share conversion price equal to $0.5450. In these transactions we also issued warrants to purchase 9,335,780 shares of the common stock in the aggregate at an exercise price per share of $0.7085. We have registered with the SEC the resale of the shares of common stock issuable upon conversion of the 2022 Notes as well as the shares of common stock issuable upon the exercise of the warrants.

- On October 19, 2022 (the "*Issuance Date*"), we issued 284,851 shares of common stock to Dr. Lynn Kirkpatrick and 636,384 shares of common stock to Dr. Bob Gower (collectively, the "*K&G Shares*"). The common stock has a per share par value of $0.0001. The K&G Shares were issued in satisfaction (reimbursement) of an obligation to a third party vendor previously incurred by the Company that was paid by Drs. Kirkpatrick and Gower. The reimbursement replaced registered but restricted shares on a one-for-one basis with unregistered and restricted shares. The aggregate market value of the K&G Shares on the Transfer Date was $210,456. The transaction involved the receipt by two insiders of unregistered and restricted shares of common stock.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise set forth above, we believe each of these transactions was exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D promulgated thereunder) as transactions by an issuer not involving any public offering or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Item 16. Exhibits and Financial Statement Schedules.

(a) *Exhibits.*

No.	Description of Exhibit
1	Underwriting Agreement
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 Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
3.1(a)	Third Amended and Restated Certificate of Incorporation of Ensysce Biosciences, Inc. (incorporated by reference to Exhibit 3.1 filed with Ensysce Biosciences, Inc.'s Current Report on Form 8-K on July 7, 2021).
3.1(b)*	Certificate of Amendment to Third Amended and Restated Certificate of Incorporation of Ensysce Biosciences, Inc.
3.2	Amended and Restated Bylaws of Ensysce Biosciences, Inc. (incorporated by reference to Exhibit 3.2 filed with Ensysce's Biosciences, Inc.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 a 2021 Securities Purchase Agreement (incorporated by reference to Exhibit 4.6 filed with the Company's Current Report on Form 8-K on September 27, 2021).
4.7	Form of Common Stock Purchase Warrant issued by the Company pursuant to and in accordance with a 2021 Securities Purchase Agreement (incorporated by reference to Exhibit 4.7 filed with the Company's Current Report on Form 8-K on September 27, 2021).
4.8	Form of Senior Secured Convertible Promissory Note issued by the Company pursuant to and in accordance with a 2022 Securities Purchase Agreement (incorporated by reference to Exhibit 4.6 filed with the Company's Current Report on Form 8-K on August 9, 2022).
4.9	Form of Common Stock Purchase Warrant issued by the Company pursuant to and in accordance with a 2022 Securities Purchase Agreement (incorporated by reference to Exhibit 4.7 filed with the Company's Current Report on Form 8-K on August 9, 2022).
4.10	Form of Series A/B warrant in connection with this offering.
4.11	Form of Pre-funded warrant in connection with this offering.
5.1	Opinion of Troutman Pepper Hamilton Sanders LLP
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 Company'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 the Registrant and HG Vora Special Opportunities Master Fund, Ltd (incorporated by reference to Exhibit 10.4 filed with the Company'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'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 Leisure Acquisition Corp.'s Current Report on Form 8-K on February 2, 2021).

10.15	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 Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.16	Employment Offer Letter to Richard Wright dated July 31, 2017 (incorporated by reference to Exhibit 10.24 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.17	Consulting Agreement between the Company and Geoff Birkett effective as of July 8, 2018 (incorporated by reference to Exhibit 10.25 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.18	Employment Agreement between the Company and David Humphrey dated February 11, 2021 (incorporated by reference to Exhibit 10.26 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.19	Amendment to Offer Letter between the Company and David Humphrey dated February 23, 2021 (incorporated by reference to Exhibit 10.27 filed with the Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.20(a)	Amended and Restated 2021 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.22 filed with Ensysce Biosciences, Inc.'s Annual Report on Form 10-K filed on March 31, 2022).
10.20(b)	Amended and Restated 2021 Omnibus Incentive Plan Form of Stock Option Grant Notice and Award Agreement (incorporated by reference to Exhibit 10.22(a) filed with Ensysce Biosciences, Inc.'s Annual Report on Form 10-K filed on March 31, 2022).
10.21	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 Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.22†	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 Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.23	Manufacturing Agreement between Recro Gaineville LLC and the Company dated September 11, 2019 (incorporated by reference to Exhibit 10.35 filed with Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.24	Manufacturing Agreement between Johnson Matthey Pharmaceutical Material, Inc. and the Company dated April 7, 2022 (portions of this exhibit have been omitted).
10.25(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 Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.25(b)	Form of Exchange Agreement 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 Company's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.26	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 Leisure Acquisition Corp.'s Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).
10.27(a)	Engagement Agreement with David L. Kovacs (incorporated by reference to Exhibit 10.37 filed with the Company's Registration Statement on Form S-1 (File No.333-258609) initially filed on August 9, 2021).
10.27(b)	Stock Option Grant Notice and Award Agreement granted February 14, 2022 to David L. Kovacs (incorporated by reference to Exhibit 10.31(b) filed with the Company's Annual Report on Form 10-K on March 31, 2022)
10.28(a)	Engagement Agreement with Mercury FundingCo, LLC (incorporated by reference to Exhibit 10.37 filed with the Company's Registration Statement on Form S-1 (File No.333-258609) initially filed on August 9, 2021).
10.28(b)	Stock Option Grant Notice and Award Agreement granted February 14, 2022 to David Tanzer (incorporated by reference to Exhibit 10.32(b) filed with the Company's Annual Report on Form 10-K on March 31, 2022).
10.29†	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 Company's Current Report on Form 8-K on September 27, 2021).
10.30	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 Company's Current Report on Form 8-K on September 27, 2021).
10.31	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 Company's Current Report on Form 8-K on September 27, 2021).

10.32†	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 Company's Current Report on Form 8-K on September 27, 2021).
10.33†	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 Company's Current Report on Form 8-K on September 27, 2021).
10.34	Securities Purchase Agreement, dated June 30, 2022, by and among the Company and the purchasers signatory thereto (incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K on July 6, 2022).
10.35	Registration Rights Agreement, dated June 30, 2022, by and among the Company and the parties signatory thereto (incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K on July 6, 2022).
10.36	Subsidiary Guarantee, dated June 30, 2022, by and among the Company and the purchasers signatory thereto (incorporated by reference to Exhibit 10.3 filed with the Company's Current Report on Form 8-K on July 6, 2022).
10.37	Security Agreement, dated June 30, 2022, 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 Company's Current Report on Form 8-K on July 6, 2022).
10.38	Patent Security Agreement, dated June 30, 2022, 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 Company's Current Report on Form 8-K on July 6, 2022).

10.39	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 Company's Annual Report on Form 10-K on March 31, 2022).
10.40	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 Company's Annual Report on Form 10-K on March 31, 2022).
10.41	Letter Agreement, dated September 20, 2022, by and among the Company and parties signatory thereto (incorporated by reference to Exhibit 10.6 filed with the Company's Current Report on Form 8-K on September 20, 2022).
21*	List of Subsidiaries
23.1	Consent of Troutman Pepper Hamilton Sanders LLP (included in Exhibit 5.1)
23.2	Consent of Mayer Hoffman McCann P.C.
24.1*	Power of Attorney (included on signature page to this registration statement)
(101)	Interactive Data File
++	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH++	Inline XBRL Taxonomy Extension Schema Document
101.CAL++	Inline XBRL Taxonomy Extension Calculation Document
101.LAB++	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE++	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF++	Inline XBRL Taxonomy Extension Definition Linkbase Document
107*	Filing Fee Table

* Previously filed.

† 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.

++ Pursuant to Rule 406T of Regulation S-T, this interactive data file is deemed not "*filed*" or part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act, is deemed not "*filed*" for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement: (i) to include any prospectus required by Section 10(a)(3) of the Securities Act; (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement (notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "*Calculation of Registration Fee*" table in the effective registration statement); and (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of securities, in a primary offering of securities of the registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser: (i) any preliminary prospectus or prospectus of the registrant relating to the offering required to be filed pursuant to Rule 424; (ii) any free writing prospectus relating to the offering prepared by or on behalf of the registrant or used or referred to by the registrant; (iii) the portion of any other free writing prospectus relating to the offering containing material information about the registrant or its securities provided by or on behalf of the registrant; and (iv) any other communication that is an offer in the offering made by the registrant to the purchaser.

(5) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(6) That, prior to any public reoffering of the securities registered hereunder through use of a prospectus which is a part of this registration statement, by any person or party who is deemed to be an underwriter within the meaning of Rule 145(c), the registrant undertakes that such reoffering prospectus will contain the information called for by the applicable registration form with respect to reofferings by persons who may be deemed underwriters, in addition to the information called for by the other items of the applicable form.

(8) That every prospectus (i) that is filed pursuant to the immediately preceding paragraph, or (ii) that purports to meet the requirements of Section 10(a)(3) of the Securities Act and is used in connection with an offering of securities subject to Rule 415, will be filed as a part of an amendment to the registration statement and will not be used until such amendment has become effective, and that for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(9) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(10) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this amendment to the registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in San Diego, State of California, on November 16, 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 Act, this amendment to the registration statement has been signed by the following persons in the capacities indicated on November 16, 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: * Andrew Benton	Director
By: * William Chang	Director
By: * Bob Gower	Director and Chairman of the Board
By: * Adam Levin	Director
By: * Steve Martin	Director
By: * Lee Rauch	Director
By: * Curtis Rosebraugh	Director

* */s/ Dr. Lynn Kirkpatrick*
By Dr. Lynn Kirkpatrick
Attorney-in-fact

Exhibit 1

ENSYSCE BIOSCIENCES, INC.

[●] Shares of Common Stock
Pre-Funded Warrants to Purchase up to [●] Shares of Common Stock
Series A Warrants to Purchase up to [●] Shares of Common Stock
Series B Warrants to Purchase up to [●] Shares of Common Stock

UNDERWRITING AGREEMENT

[●], 2022

Lake Street Capital Markets, LLC
920 Second Avenue South, Suite 700
Minneapolis, Minnesota 55402

Ladies and Gentlemen:

Ensysce Biosciences, Inc., a Delaware corporation (the "Company"), proposes, subject to the terms and conditions contained in this Underwriting Agreement (the "Agreement"), to sell to you (the "Underwriter"), an aggregate of (i) [●] shares (the "Firm Shares") of the Company's common stock, $0.0001 par value per share (the "Common Stock"), (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of [●] shares of Common Stock (the "Pre-Funded Warrant Shares"), (iii) Series A warrants (the "Firm Series A Warrants") to purchase up to an aggregate of [●] shares of Common Stock (the "Firm Series A Warrant Shares") and (iv) Series B warrants (the "Firm Series B Warrants") to purchase up to an aggregate of [●] shares of Common Stock (the "Firm Series B Warrant Shares). The Firm Shares, the Pre-Funded Warrants, the Pre-Funded Warrant Shares, the Firm Series A Warrants, the Firm Series B Warrants, the Firm Series A Warrant Shares and the Firm Series B Warrant Shares are collectively referred to as the "Firm Securities." The Company also proposes to issue and sell to the Underwriter, upon the terms and conditions set forth herein, up to an additional (i) [●] shares of Common Stock (the "Option Shares", and together with the Firm Shares, the "Shares"), and/or Series A warrants (the "Option Series A Warrants" and together with the Firm Series A Warrants, the "Series A Warrants") to purchase up to an aggregate of [●] shares of Common Stock (the "Option Series A Warrant Shares") and/or Series B warrants (the "Option Series B Warrants" and together with the Firm Series B Warrants, the "Series B Warrants") to purchase up to an aggregate of [●] shares of Common Stock (the "Option Series B Warrant Shares"). The Option Shares, the Option Series A Warrants, the Option Series B Warrants, the Option Series A Warrant Shares and the Option Series B Warrant Shares are collectively referred to as the "Option Securities." The Series A Warrants and the Series B Warrants are collectively referred to as the "Warrants." The Pre-Funded Warrant Shares, the Firm Series A Warrant Shares, the Firm Series B Warrant Shares, the Option Series A Warrant Shares and the Option Series B Warrant Shares are collectively referred to as the "Warrant Shares." The Firm Securities and the Option Securities are collectively referred to as the "Securities."

The Firm Shares and/or Pre-Funded Warrants, the Firm Series A Warrants and the Firm Series B Warrants will be issued in a fixed combination of one Firm Share or Pre-Funded Warrant, one Firm Series A Warrant and one Firm Series B Warrant. The Firm Shares and/or Pre-Funded Warrants, the Firm Series A Warrants and the Firm Series B Warrants will be sold together but will be immediately separable and transferable upon issuance. The Option Shares, Option Series A Warrants and/or the Option Series B Warrants may be sold from time to time either together or separately in any combination to be determined by the Underwriter.

The terms of the Pre-Funded Warrants are set forth in the form of Pre-Funded Warrant attached hereto as **Exhibit B**. The terms of the Series A Warrants are set forth in the form of Series A Warrant attached hereto as **Exhibit C**. The terms of the Series B Warrants are set forth in the form of Series B Warrant attached hereto as **Exhibit D**.

The Company has prepared and filed in conformity with the requirements of the Securities Act of 1933, as amended (the "Securities Act"), and the published rules and regulations thereunder (the "Rules") adopted by the Securities and Exchange Commission (the "Commission") a Registration Statement (as hereinafter defined), including a Preliminary Prospectus (as hereinafter defined) relating to the Securities, and such amendments thereof as may have been required to the date of this Agreement. Copies of such Registration Statement (including all amendments thereof) and of the related Preliminary Prospectus have heretofore been delivered by the Company to the Underwriter. The term "Preliminary Prospectus" means any preliminary prospectus included at any time as a part of the Registration Statement or filed with the Commission by the Company pursuant to Rule 424(a) of the Rules. The term "Registration Statement" as used in this Agreement means the initial registration statement on Form S-1 (No. 333-268038) (including all exhibits, financial schedules and all documents and information deemed to be a part of the Registration Statement through incorporation by reference or otherwise), as amended at the time and on the date it becomes effective (the "Effective Date"), including the information (if any) contained in the final prospectus filed with the Commission pursuant to Rule 424(b) of the Rules and deemed to be part thereof at the time of effectiveness pursuant to Rule 430A of the Rules. If the Company has filed an abbreviated registration statement to register additional Securities pursuant to Rule 462(b) under the Rules (the "462(b) Registration Statement"), then any reference herein to the Registration Statement shall also be deemed to include such 462(b) Registration Statement. The term "Prospectus" as used in this Agreement means the final prospectus filed with the Commission pursuant to and within the time limits described in Rule 430A and 424(b) of the Rules.

The Company understands that the Underwriter proposes to make a public offering of the Underwritten Securities (as defined below), as set forth in and pursuant to the Statutory Prospectus (as defined below) and the Prospectus, as soon after the Effective Date and the date of this Agreement as the Underwriter deems advisable. The Company hereby confirms that the Underwriter and dealers have been authorized to distribute or cause to be distributed each Preliminary Prospectus and are authorized to distribute the Prospectus (as from time to time amended or supplemented if the Company furnishes amendments or supplements thereto to the Underwriter).

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1. Sale, Purchase, Delivery and Payment for the Underwritten Securities. On the basis of the representations, warranties and agreements contained in, and subject to the terms and conditions of, this Agreement:

(a) The Company agrees to issue and sell to the Underwriter, and the Underwriter agrees to purchase from the Company, at a combined purchase price of $[●] per Firm Share and accompanying Firm Series A Warrant and Firm Series B Warrant and $[●] per Pre-Funded Warrant and accompanying Firm Series A Warrant and Firm Series B Warrant, (i) the Firm Shares, (ii) the Pre-Funded Warrants, (iii) the Firm Series A Warrants, and (iv) the Firm Series B Warrants (such Securities, collectively, the "Underwritten Firm Securities").

(b) The Company hereby grants to the Underwriter an option to purchase, all or any part of the Option Shares at a price per share equal to $[●], and/or all or any part of the Option Series A Warrants at $0.0093 per Option Series A Warrant Share and/or all or any part of the Option Series B Warrants at $0.0093 per Option Series B Warrant Shares (such Securities, collectively the "Underwritten Option Securities"). The Underwritten Firm Securities and the Underwritten Option Securities are collectively referred to herein as the "Underwritten Securities"). Such option may be exercised only to cover over-allotments in the sales of the Underwritten Firm Securities by the Underwriter and may be exercised in whole or in part at any time on or before 12:00 noon, New York City time, on the business day before the Firm Securities Closing Date (as defined below), and from time to time thereafter

within 45 days after the Firm Securities Closing Date, in each case upon written or electronic notice, or verbal or telephonic notice confirmed by written or electronic notice, by the Underwriter to the Company no later than 12:00 noon New York City time on the business day before the Firm Securities Closing Date (as defined below) or at least one business day before the Option Securities Closing Date (as defined below), as the case may be, setting forth the number of Option Shares, Option Series A Warrants and/or Option Series B Warrants to be purchased and the time and date (if other than the Firm Securities Closing Date) of such purchase.

(c) Payment of the purchase price for, and delivery of, the Firm Underwritten Securities shall be made at the offices of Lake Street Capital Markets, LLC, 920 Second Avenue South, Suite 700, Minneapolis, Minnesota 55402, at 10:00 a.m., New York City time, on [●], 2022, or at such time on such other date, not later than five (5) business days after the date of this Agreement, as shall be agreed upon by the Company and the Underwriter (such time and date of delivery and payment are called the "Firm Securities Closing Date"). In the event that a purchaser delivers a Notice of Exercise (as defined in the Pre-Funded Warrants) on or prior to 4:00 p.m., New York City time on the business day prior to the Firm Securities Closing Date, to exercise any Pre-Funded Warrants between the date hereof and the Firm Securities Closing Date, the Company shall deliver Pre-Funded Warrant Shares with respect to such Pre-Funded Warrants to such purchaser on the Firm Securities Closing Date in connection with such Notice of Exercise. In addition, in the event that any or all of the Underwritten Option Securities are purchased by the Underwriter, payment of the purchase price for, and deliver of such Underwritten Option Securities, shall be made at the above-mentioned offices, or at such other place as shall be agreed upon by the Underwriter and the Company, on each date of delivery as specified in the notice from the Underwriter to the Company (such time and date of delivery and payment are called the "Option Securities Closing Date"). The Firm Securities Closing Date and any Option Securities Closing Date are called, individually, a "Closing Date" and, together, the "Closing Dates."

(d) Payment shall be made to the Company by wire transfer of immediately available funds or by certified or official bank check or checks payable in New York Clearing House (same day) funds drawn to the order of the Company against delivery of the Underwritten Firm Securities or Underwritten Option Securities, as applicable, to the account of the Underwriter.

(e) The Underwritten Securities shall be registered in such names and shall be in such denominations as the Underwriter shall request at least one (1) full business day before the Closing Date (or the Option Securities Closing Date in the case of the Underwritten Option Securities). The Shares shall be delivered by or on behalf of the Company to the Underwriter through the facilities of the Depository Trust Company for the account of the Underwriter. Delivery of the Pre-Funded Warrants, Series A Warrants and Series B Warrants shall be made by physical delivery to be received or directed by the Underwriter no later than one (1) business day following the Closing Date or Option Closing Date, as applicable.

2. Representations and Warranties of the Company. The Company represents and warrants to the Underwriter as of the date hereof and as of the Firm Securities Closing Date and as of each Option Securities Closing Date (if any) as follows:

(a) On the Effective Date, the Registration Statement complied, and on the date of the Prospectus, the date any post-effective amendment to the Registration Statement becomes effective, the date any supplement or amendment to the Prospectus is filed with the Commission and each Closing Date, the Registration Statement, the Prospectus (and any amendment thereof or supplement thereto) will comply, in all material respects, with the requirements of the Securities Act, the Rules, the Exchange Act and the rules and regulations of the Commission thereunder. The Registration Statement did not, as of the Effective Date, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading; and on the Effective Date and the other dates referred to above neither the Registration Statement nor the Prospectus, nor any amendment thereof or supplement thereto, will contain any untrue statement of a material fact or will omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading. When any Preliminary Prospectus was first filed with the Commission (whether filed as part of the Registration Statement or any amendment thereto or pursuant to Rule 424(a) of the Rules) and when any amendment thereof or supplement thereto was first filed with the Commission, such Preliminary Prospectus as amended or supplemented complied in all material respects with the applicable provisions of the Securities Act and the Rules and did not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. If applicable, each Preliminary Prospectus and the Prospectus delivered to the Underwriter for use in connection with this offering was identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T. Notwithstanding the foregoing, none of the representations and warranties in this paragraph 2(a) shall apply to statements in, or omissions from, the Registration Statement, any Preliminary Prospectus or the Prospectus made in reliance upon, and in conformity with, information herein or otherwise furnished in writing by the Underwriter specifically for use in the Registration Statement, any Preliminary Prospectus or the Prospectus, as the case may be. With respect to the preceding sentence, the Company acknowledges that the only information furnished in writing by the Underwriter for use in the Registration Statement, any Preliminary Prospectus or the Prospectus is the statements contained in the fifth and eleventh paragraphs under the caption "Underwriting" in the Prospectus (collectively, the "Underwriter Information").

(b) As of the Applicable Time (as hereinafter defined), none of the price to the public and the number of Firm Shares, Pre-Funded Warrants, Firm Series A Warrants and Firm Series B Warrants offered and sold, as indicated on the cover page of the Prospectus and the Statutory Prospectus, all considered together (collectively, the "General Disclosure Package") included, includes or will include any untrue statement of a material fact or omitted, omits or will omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to statements in or omissions in the General Disclosure Package made in reliance upon and in conformity with the Underwriter Information.

As used in this Section and elsewhere in this Agreement:

"Applicable Time" means [●] [a.m.]/[p.m.] (Eastern time) on the date of this Agreement.

"Statutory Prospectus" as of any time means the Preliminary Prospectus relating to the Securities that is included in the Registration Statement immediately prior to the Applicable Time.

(c) The Registration Statement is effective under the Securities Act and no stop order preventing or suspending the effectiveness of the Registration Statement or suspending or preventing the use of any Preliminary Prospectus or the Prospectus has been issued by the Commission and no proceedings for that purpose have been instituted, or, to the Company's knowledge, are threatened under the Securities Act. Any required filing of any

Preliminary Prospectus and/or the Prospectus and any supplement thereto pursuant to Rule 424(b) of the Rules has been or will be made in the manner and within the time period required by such Rule 424(b).

(d) The financial statements of the Company (including all notes and schedules thereto) included in the Registration Statement, the Statutory Prospectus and Prospectus present fairly, in all material respects, the financial position of the Company and its consolidated subsidiaries at the dates indicated and the statements of operations, stockholders' equity (deficit) and statements of cash flows of the Company and its consolidated subsidiaries for the periods specified; and such financial statements and related schedules and notes thereto, and the unaudited financial information filed with the Commission as part of the Registration Statement, have been prepared in conformity with generally accepted accounting principles ("GAAP"), consistently applied throughout the periods involved. The summary and selected financial data included in the Statutory Prospectus and Prospectus present fairly, in all material respects, the information shown therein as at the respective dates and for the respective periods specified and have been presented on a basis consistent with the consolidated financial statements set forth in the Prospectus and other financial information.

(e) Mayer Hoffman McCann P.C. (the "Auditor") whose reports are filed with the Commission as a part of the Registration Statement, are and, during the periods covered by their reports, were independent public accountants with respect to the Company as required by the Securities Act and the Rules.

(f) The Company and each of its subsidiaries, including each entity (corporation, partnership, joint venture, association or other business organization) controlled directly or indirectly by the Company (each, a "subsidiary"), are duly organized, validly existing and in good standing under the laws of their respective jurisdictions of incorporation or organization and each such entity has all requisite power and authority to carry on its business as is currently being conducted as described in the Statutory Prospectus and the Prospectus, and to own, lease and operate its properties. All of the issued shares of capital stock of, or other ownership interests in, each subsidiary have been duly and validly authorized and issued and are fully paid and non-assessable and are owned, directly or indirectly, by the Company, free and clear of any lien, charge, mortgage, pledge, security interest, claim, limitation on voting rights, equity, trust or other encumbrance, preferential arrangement, defect or restriction of any kind whatsoever, other than as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus. The Company and each of its subsidiaries is duly qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the nature of the business conducted by it or location of the assets or properties owned, leased or licensed by it requires such qualification, except for such jurisdictions where the failure to so qualify individually or in the aggregate would not have a material adverse effect on the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company and its subsidiaries considered as a whole (a "Material Adverse Effect"); and to the Company's knowledge, no proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing, or seeking to revoke, limit or curtail, such power and authority or qualification.

(g) The Company and each of its subsidiaries has all requisite corporate power and authority, and all necessary authorizations, approvals, consents, orders, licenses, certificates and permits of and from all governmental or regulatory bodies or any other person or entity (collectively, the "Permits"), to own, lease and license its assets and properties and conduct its business, all of which are valid and in full force and effect, except where the lack of such Permits, individually or in the aggregate, would not have a Material Adverse Effect. The Company and each of its subsidiaries has fulfilled and performed, in all material respects, all of its obligations with respect to such Permits and no event has occurred that allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other material impairment of the rights of the Company thereunder. Except as may be required under the Securities Act and state and foreign Blue Sky laws, no other Permits are required to enter into, deliver and perform this Agreement and to issue and sell the Securities.

(h) (i) At the time of filing the Registration Statement, and (ii) as of the date hereof, the Company was an "ineligible issuer," as defined in Rule 405 of the Rules, solely as a result of the provisions in Rule 405(1)(ii)(A).

(i) The Company and each of its subsidiaries owns or possesses legally enforceable rights to use all patents, patent applications, inventions, trademarks, trademark applications, trade names, service marks, copyrights, copyright applications, licenses, know-how and other similar intellectual property rights and proprietary knowledge (collectively, "Intangibles") necessary for the conduct of its business as now conducted or as proposed to be conducted, as described in the Registration Statement, General Disclosure Package and Prospectus. Neither the Company nor any of its subsidiaries has received any written notice of, nor is it aware of, any infringement of or conflict with asserted rights of others with respect to any Intangibles.

(j) The Company and each of its subsidiaries has good and marketable title in fee simple to all real property, and good and marketable title to all other property owned by it (excluding Intangibles referenced in (i) above), in each case free and clear of all liens, encumbrances, claims, security interests and defects, except as described in the Registration Statement, the Statutory Prospectus and the Prospectus, and such as do not materially affect the value of such property and do not materially interfere with the use made or proposed to be made of such property by the Company and its subsidiaries. All property held under lease by the Company and its subsidiaries is held by them under valid, existing and enforceable leases, free and clear of all liens, encumbrances, claims, security interests and defects, except as described in the Registration Statement, the Statutory Prospectus and the Prospectus and such as are not material and do not materially interfere with the use made or proposed to be made of such property by the Company and its subsidiaries.

(k) Subsequent to the respective dates as of which information is given in the Registration Statement, the Statutory Prospectus and the Prospectus, (i) there has not been any event which could have a Material Adverse Effect; (ii) neither the Company nor any of its subsidiaries has sustained any loss or interference with its assets, businesses or properties (whether owned or leased) from fire, explosion, earthquake, flood or other calamity, whether or not covered by insurance, or from any labor dispute or any court or legislative or other governmental action, order or decree which would have a Material Adverse Effect; and (iii) since the date of the latest balance sheet included in the Registration Statement and the Prospectus, neither the Company nor its subsidiaries has (A) issued any securities (other than securities issued pursuant to employee benefit plans, qualified stock option plans or other employee compensation plans or pursuant to outstanding options, rights or warrants or pursuant to conversion of, or redemption of obligations under, notes issued by the Company in 2022) or incurred any liability or obligation, direct or contingent, for borrowed money, except such liabilities or obligations incurred in the ordinary course of business, (B) entered into any transaction not in the ordinary course of business or (C) except for regular dividends on the Common Stock in amounts per share that are consistent with past practice, declared or paid any dividend or made any distribution on any shares of its stock or redeemed, purchased or otherwise acquired or agreed to redeem, purchase or otherwise acquire any shares of its capital stock.

(l) There is no document, contract or other agreement required to be described in the Registration Statement, the Statutory Prospectus or the Prospectus or to be filed as an exhibit to the Registration Statement which is not described or filed as required by the Securities Act or Rules. Each description of a contract, document or other agreement in the Registration Statement, the Statutory Prospectus or the Prospectus accurately reflects, in all material respects, the terms of the underlying contract, document or other agreement. Each contract, document or other agreement described in the Registration Statement, the Statutory Prospectus or the Prospectus or listed in the Exhibits to the Registration Statement is in full force and effect and is valid and enforceable by and against the Company or its subsidiary, as the case may be, in accordance with its terms. Neither the Company nor any of its subsidiaries, if a subsidiary is a party, nor to the Company's knowledge, any other party, is in default in the observance or performance of any term or obligation to be performed by it under any such agreement, and no event has occurred which with notice or lapse of time or both would constitute such a default, in any such case which default or event, individually or in the aggregate, would have a Material Adverse Effect. No default exists, and no event has occurred which with notice or lapse of time or both would constitute a default, in the due performance and observance of any term, covenant or condition, by the Company or its subsidiary, if a subsidiary is a party thereto, of any other agreement or instrument to which the Company or any of its subsidiaries is a party or by which Company or its properties or business or a subsidiary or its properties or business may be bound or affected which default or event, individually or in the aggregate, would have a Material Adverse Effect.

(m) The statistical and market related data included in the Registration Statement, the Statutory Prospectus or the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate.

(n) Neither the Company nor any subsidiary (i) is in violation of its certificate of incorporation, bylaws or other organizational documents, (ii) is in default under, and no event has occurred which, with notice or lapse of time, or both, would constitute a default under, or result in the creation or imposition of any lien, charge, mortgage, pledge, security interest, claim, limitation on voting rights, equity, trust or other encumbrance, preferential arrangement, defect or restriction of any kind whatsoever, upon, any property or assets of the Company or any subsidiary pursuant to, any bond, debenture, note, indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which it is a party or by which it is bound or to which any of its properties or assets is subject or (iii) is in violation of any statute, law, rule, regulation, ordinance, directive, judgment, decree or order of any judicial, regulatory or other legal or governmental agency or body, foreign or domestic, except (in the case of clauses (ii) and (iii) above) for violations or defaults that could not (individually or in the aggregate) reasonably be expected to have a Material Adverse Effect.

(o) This Agreement has been duly authorized, executed and delivered by the Company.

(p) Neither the execution, delivery and performance of this Agreement, the Pre-Funded Warrants and the Warrants by the Company nor the consummation of any of the transactions contemplated hereby (including, without limitation, the issuance and sale by the Company of the Securities) will give rise to a right to terminate or accelerate the due date of any payment due under, or conflict with or result in the breach of any term or provision of, or constitute a default (or an event which with notice or lapse of time or both would constitute a default) under, or require any consent or waiver under, or result in the execution or imposition of any lien, charge or encumbrance upon any properties or assets of the Company or its subsidiaries pursuant to the terms of, any indenture, mortgage, deed of trust or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which either the Company or its subsidiaries or any of their properties or businesses is bound, or any franchise, license, permit, judgment, decree, order, statute, rule or regulation applicable to the Company or any of its subsidiaries or violate any provision of the charter or by-laws of the Company or any of its subsidiaries, except for such consents or waivers which have already been obtained and are in full force and effect.

(q) The Company has authorized and outstanding capital stock as set forth under the caption "Description of Capital Stock" in the Registration Statement, the Statutory Prospectus and the Prospectus. The Securities have been duly authorized for issuance by the Company. All of the issued and outstanding shares of Common Stock have been duly and validly issued and are fully paid and nonassessable and were issued in compliance in all material respects with applicable securities laws. There are no statutory preemptive or other similar rights to subscribe for or to purchase or acquire any shares of Common Stock of the Company or any of its subsidiaries or any such rights pursuant to its Certificate of Incorporation or by-laws or any agreement or instrument to or by which the Company or any of its subsidiaries is a party or bound. The Company has reserved and kept available for the exercise of the Pre-Funded Warrants and the Warrants such number of authorized but unissued shares of Common Stock as are sufficient to permit the exercise in full of the Pre-Funded Warrants and the Warrants in accordance with their terms. The Shares, when issued and sold pursuant to this Agreement, the Pre-Funded Warrant Shares, when issued and sold pursuant to the Pre-Funded Warrants, and the Warrant Shares, when issued and sold pursuant to the Warrants, will be duly and validly issued, fully paid and nonassessable and none of them will be issued in violation of any preemptive or other similar right. Except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, there is no outstanding option, warrant or other right calling for the issuance of, and there is no commitment, plan or arrangement to issue, any share of stock of the Company or any of its subsidiaries or any security convertible into, or exercisable or exchangeable for, such stock. The exercise price of each option to acquire Common Stock (each, a "Company Stock Option") is no less than the fair market value of a share of Common Stock as determined on the date of grant of such Company Stock Option. All grants of Company Stock Options were validly issued and properly approved by the Board of Directors of the Company in material compliance with all applicable laws and the terms of the plans under which such Company Stock Options were issued and were recorded on the Company Financial Statements, in accordance with GAAP, and no such grants involved any "back dating," "forward dating," "spring loading" or similar practices with respect to the effective date of grant. The Common Stock and the Securities conform in all material respects to all statements in relation thereto contained in the Registration Statement and the Statutory Prospectus and the Prospectus. All outstanding shares of capital stock of each of the Company's subsidiaries have been duly authorized and validly issued, and are fully paid and nonassessable and are owned directly by the Company or by another wholly-owned subsidiary of the Company free and clear of any security interests, liens, encumbrances, equities or claims, other than those described in the Registration Statement, the Statutory Prospectus and the Prospectus.

(r) No holder of any security of the Company has any right, which has not been waived, to have any security owned by such holder included in the Registration Statement or to demand registration of any security owned by such holder for a period of 90 days after the date of this Agreement. Each director and executive officer of the Company listed on Schedule II hereto has delivered to the Underwriter his or her enforceable written lock-up agreement in the form attached to this Agreement as **Exhibit A** hereto ("Lock-up Agreement").

(s) There are no legal or governmental proceedings pending to which the Company or any of its subsidiaries is a party or of which any property of the Company or any of its subsidiaries is the subject which, if determined adversely to the Company or any of its subsidiaries could individually or in the aggregate have a Material Adverse Effect; and, to the knowledge of the Company, no such proceedings are threatened or contemplated by governmental authorities or threatened by others.

(t) All necessary corporate action has been duly and validly taken by the Company to authorize the execution, delivery and performance of this Agreement, the Pre-Funded Warrants and the Warrants and the issuance and sale of the Securities by the Company. The Warrants and Pre-Funded Warrants on the Closing Date will be, duly and validly authorized, executed and delivered by the Company and will constitute legal, valid and binding

obligations of the Company enforceable against the Company in accordance with their respective terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, and (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

(u) The Company nor any of its subsidiaries is involved in any labor dispute nor, to the knowledge of the Company, is any such dispute threatened, in each case, which dispute would have a Material Adverse Effect. The Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers or contractors which would have a Material Adverse Effect. The Company is not aware of any threatened or pending litigation between the Company or its subsidiaries and any of its executive officers which, if adversely determined, could have a Material Adverse Effect, and the Company has no reason to believe that such executive officers will not remain in the employment of the Company.

(v) No transaction has occurred between or among the Company and any of its officers or directors, stockholders or any affiliate or affiliates of any such officer or director or stockholder that is required to be described in and is not described in the Registration Statement, the Statutory Prospectus and the Prospectus.

(w) The Company has not taken, nor will it take, directly or indirectly, any action designed to or which might reasonably be expected to cause or result in, or which has constituted or which might reasonably be expected to constitute, the stabilization or manipulation of the price of the Common Stock or any security of the Company to facilitate the sale or resale of any of the Underwritten Securities.

(x) The Company and each of its subsidiaries has filed all federal, state, local and foreign tax returns which are required to be filed through the date hereof, which returns are true and correct in all material respects or has received timely extensions thereof, and has paid all taxes shown on such returns and all assessments received by it to the extent that the same are material and have become due. There are no tax audits or investigations pending, which if adversely determined would have a Material Adverse Effect; nor are there any material proposed additional tax assessments against the Company or any of its subsidiaries.

(y) The Common Stock is registered pursuant to Section 12(b) of the Exchange Act and listed on The Nasdaq Capital Market. The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or the quotation of the Common Stock on The Nasdaq Capital Market, nor, except as described in the Registration Statement, the Statutory Prospectus and the Prospectus, has the Company received any notification that the Commission or The Nasdaq Capital Market is contemplating terminating such registration or quotation.

(z) The books, records and accounts of the Company and its subsidiaries accurately and fairly reflect, in all material respects, the transactions in, and dispositions of, the assets of, and the results of operations of, the Company and its subsidiaries. The Company and each of its subsidiaries maintains a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(aa) The Company has established and maintains disclosure controls and procedures (as such term is defined in Rule 13a-15(e) under the Exchange Act), which: (i) are designed to ensure that material information relating to the Company is made known to the Company's principal executive officer and its principal financial officer by others within the Company, particularly during the periods in which the periodic reports required under the Exchange Act are required to be prepared; (ii) provide for the periodic evaluation of the effectiveness of such disclosure controls and procedures at the end of the periods in which the periodic reports are required to be prepared; and (iii) are effective in all material respects to perform the functions for which they were established.

(bb) Based on the evaluation of its disclosure controls and procedures, the Company is not aware of (i) any material weakness or significant deficiency in the design or operation of internal controls, except as described in the Registration Statement, the Statutory Prospectus and the Prospectus, which could adversely affect the Company's ability to record, process, summarize and report financial data or any material weaknesses in internal controls; or (ii) any fraud, whether or not material, that involves management or other employees who have a role in the Company's internal controls.

(cc) Except as described in the Registration Statement, the Statutory Prospectus and the Prospectus and as preapproved in accordance with the requirements set forth in Section 10A of the Exchange Act, the Auditor has not been engaged by the Company to perform any "prohibited activities" (as defined in Section 10A of the Exchange Act).

(dd) Except as described in the Registration Statement, the Statutory Prospectus and the Prospectus, there are no material off-balance sheet arrangements (as defined in Item 303 of Regulation S-K) that have or are reasonably likely to have a material current or future effect on the Company's financial condition, revenues or expenses, changes in financial condition, results of operations, liquidity, capital expenditures or capital resources.

(ee) The Company's Board of Directors has validly appointed an audit committee whose composition satisfies the requirements of Rule 5605 of the Nasdaq Stock Market and the Board of Directors and/or the audit committee has adopted a charter that satisfies the requirements of Rule 5605 of The Nasdaq Stock Market. The audit committee has reviewed the adequacy of its charter within the past twelve (12) months.

(ff) There is and has been no failure on the part of the Company or any of its directors or officers, in their capacities as such, to comply with any provision of the Sarbanes-Oxley Act of 2002, as applicable, including, without limitation, Section 402 related to loans and Sections 302 and 906 related to certifications.

(gg) The Company and its subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are customary in the businesses in which they are engaged or propose to engage after giving effect to the transactions described in the

Statutory Prospectus and the Prospectus; all policies of insurance and fidelity or surety bonds insuring the Company or any of its subsidiaries or the Company's or its subsidiaries' respective businesses, assets, employees, officers and directors are in full force and effect; the Company and each of its subsidiaries are in compliance with the terms of such policies and instruments in all material respects; and neither the Company nor any subsidiary of the Company has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that is not materially greater than the current cost. Neither the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.

(hh) Each approval, consent, order, authorization, designation, declaration or filing of, by or with any regulatory, administrative or other governmental body necessary in connection with the execution and delivery by the Company of this Agreement and the consummation of the transactions herein contemplated required to be obtained or performed by the Company (except (i) such additional steps as may be required by the Financial Industry Regulatory Authority ("FINRA"); (ii) as may be necessary to qualify the Underwritten Securities for public offering by the Underwriter under the state securities or Blue Sky laws; (iii) the filing of a Notification Form: Listing of Additional Shares with The Nasdaq Capital Market; or (iv) any filings required under the Exchange Act, which have been or will be made when and how required) has been obtained or made and is in full force and effect.

(ii) None of the Company, nor any of its officers, directors or, to the best knowledge of the Company, any beneficial owner of five percent or greater of the Common Stock, is affiliated or associated with any broker-dealer that is a member of FINRA, except as otherwise disclosed to the Underwriter in writing.

(jj) (i) Each of the Company and each of its subsidiaries is in compliance in all material respects with all rules, laws and regulation relating to the use, treatment, storage and disposal of toxic substances and protection of health or the environment ("Environmental Laws") which are applicable to its business; (ii) neither the Company nor its subsidiaries has received any notice from any governmental authority or third party of an asserted claim under Environmental Laws; (iii) each of the Company and each of its subsidiaries has received all permits, licenses or other approvals required of it under applicable Environmental Laws to conduct its business, except where the lack of such permits, licenses or other approvals, individually or in the aggregate, would not have a Material Adverse Effect, and is in compliance, in all material respects, with all terms and conditions of any such permit, license or approval; (iv) to the Company's knowledge, no facts currently exist that will require the Company or any of its subsidiaries to make future material capital expenditures to comply with Environmental Laws; and (v) no property which is or has been owned, leased or occupied by the Company or its subsidiaries has been designated as a Superfund site pursuant to the Comprehensive Environmental Response, Compensation of Liability Act of 1980, as amended (42 U.S.C. Section 9601, et. seq.) ("CERCLA 1980") or otherwise designated as a contaminated site under applicable state or local law. Neither the Company nor any of its subsidiaries has been named as a "potentially responsible party" under the CERCLA 1980.

(kk) In the ordinary course of its business, the Company periodically reviews the effect of Environmental Laws on the business, operations and properties of the Company and its subsidiaries, in the course of which the Company identifies and evaluates associated costs and liabilities (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws, or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties). On the basis of such review, the Company has reasonably concluded that such associated costs and liabilities would not, singly or in the aggregate, have a Material Adverse Effect.

(ll) The Company is not and, after giving effect to the offering and sale of the Securities and the application of proceeds thereof as described in the Statutory Prospectus and the Prospectus, will not be an "investment company" within the meaning of the Investment Company Act of 1940, as amended (the "Investment Company Act").

(mm) The Company, any director, officer or employee of the Company or its subsidiaries, and, to the knowledge of the Company, any agent or other person acting on behalf of the Company or its subsidiaries, has not, directly or indirectly, while acting on behalf of the Company or its subsidiaries (i) used any corporate funds for unlawful contributions, gifts, entertainment or other unlawful expenses relating to political activity; (ii) made any unlawful payment to foreign or domestic government officials or employees or to foreign or domestic political parties or campaigns from corporate funds; (iii) violated any applicable provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended; or (iv) made any other unlawful payment.

(nn) The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending, or to the best knowledge of the Company, threatened.

(oo) Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee or affiliate of the Company or any of its subsidiaries is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"); and the Company will not directly or indirectly use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(pp) Except as described in the Registration Statement, the Statutory Prospectus and the Prospectus, the Company has not sold or issued any shares of Common Stock during the six-month period preceding the date of the Prospectus, including any sales pursuant to Rule 144A under, or Regulations D or S of, the Securities Act, other than shares issued pursuant to employee benefit plans, qualified stock options plans or other employee compensation plans or pursuant to outstanding options, rights, warrants or debt securities.

(qq) The Company has fulfilled its obligations, if any, under the minimum funding standards of Section 302 of the U.S. Employee Retirement Income Security Act of 1974 ("ERISA") and the regulations and published interpretations thereunder with respect to each "plan" as defined in Section 3(3) of ERISA and such regulations and published interpretations in which its employees are eligible to participate and each such plan is in compliance, in all material respects, with the presently applicable provisions of ERISA and such regulations and published interpretations. No "Reportable Event" (as defined in 12 ERISA) has occurred with respect to any "Pension Plan" (as defined in ERISA) for which the Company could have any liability.

(rr) None of the Company, its directors or its officers has distributed nor will distribute prior to the later of (i) the Firm Securities Closing Date, or the Option Securities Closing Date, and (ii) completion of the distribution of the Securities, any offering material in connection with the offering and sale of the Securities other than any Preliminary Prospectus, the Prospectus and the Registration Statement.

(ss) Since the date of the preliminary prospectus included in the Registration Statement filed with the Commission on October 28, 2022 (or, if earlier, the first date on which the Company engaged directly or through any person authorized to act on its behalf in any Testing-the-Waters Communication (as defined herein)) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "Emerging Growth Company"). "Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act.

(tt) The Company (a) has not alone engaged in any Testing-the-Waters Underwriter other than Testing-the-Waters Communications with the consent of the Underwriter with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act and (b) has not authorized anyone other than the Underwriter to engage in Testing-the-Waters Communications. The Company reconfirms that the Underwriter has been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications (as defined herein). "Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act.

(uu) The Company and its subsidiaries: (A) are and at all times have been in compliance with all statutes, rules, and regulations applicable to Company and its subsidiaries related to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company ("Applicable Laws"), except as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect; (B) have not received any U.S. Food and Drug Administration ("FDA") Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from any governmental authority alleging or asserting noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws ("Authorizations"); (C) possess all material Authorizations and such Authorizations are valid and in full force and effect and are not in material violation of any term of any such Authorizations; (D) have not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority or third party alleging that any product operation or activity is in violation of any Applicable Laws or Authorizations and have no knowledge that any such governmental authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (E) have not received notice that any governmental authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations and the Company has no knowledge that any such governmental authority is considering such action; (F) have not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety, efficacy or regulatory compliance of any product or any alleged product defect or violation and, to the Company's knowledge, no third party has initiated or conducted any such notice or action and there are no facts which are reasonably likely to cause, and the Company has not received any written notice from the FDA or any other regulatory agency regarding, a material recall, market withdrawal or replacement of any Company product sold or intended to be sold by the Company, a material change in the marketing classification or a material adverse change in the labeling of any such Company products, or a termination or suspension of the manufacturing, marketing, or distribution of such Company products; and (G) have filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct in all material respects on the date filed (or were corrected or supplemented by a subsequent submission).

(vv) The studies, tests and preclinical and clinical investigations conducted by or on behalf of the Company and its subsidiaries were and, if still pending, are, in all material respects, being conducted in accordance with established protocols, procedures and controls pursuant to accepted professional scientific standards and all Applicable Laws and Authorizations, including, without limitation, the Federal Food, Drug, and Cosmetic Act and implementing regulations including good laboratory practice ("GLP") regulations (21 C.F.R. Part 58) if any such studies, tests or preclinical and clinical investigations are being conducted pursuant to GLP, and good clinical practice and IND requirements (21 C.F.R. Parts 50, 54, 56, and 312) if any such studies, tests or preclinical and clinical investigations were or are subject to good clinical practice regulations or were or are being conducted under an IND; the descriptions of the results of such studies, tests and trials contained in the Registration Statement, the Statutory Prospectus and the Prospectus are accurate in all material respects and fairly present the data derived from such studies, tests and trials. The Company is not aware of any studies, tests or trials the results of which the Company believes reasonably call into question the study, test, or trial results described or referred to in the Registration Statement, the Statutory Prospectus and the Prospectus when viewed in the context in which such results are described and the clinical state of development; and neither the Company nor any of its subsidiaries have received any notices or correspondence from any governmental authority requiring the termination, suspension or material modification of any studies, tests or preclinical or clinical investigations conducted by or on behalf of the Company or any of its subsidiaries.

3. Conditions of the Underwriter's Obligations. The obligation of the Underwriter to purchase the Underwritten Firm Securities or any Underwritten Option Securities, as applicable, is subject to each of the following terms and conditions:

(a) Notification that the Registration Statement has become effective shall have been received by the Underwriter and the Prospectus shall have been timely filed with the Commission in accordance with Section 4(a) of this Agreement and any material required to be filed by the Company pursuant to Rule 433(d) of the Rules shall have been timely filed with the Commission in accordance with such rule.

(b) No order preventing or suspending the use of any Preliminary Prospectus or the Prospectus shall have been or shall be in effect and no order suspending the effectiveness of the Registration Statement shall be in effect and no proceedings for such purpose shall be pending before or threatened by the Commission, and any requests for additional information on the part of the Commission (to be included in the Registration Statement or the Prospectus or otherwise) shall have been complied with to the satisfaction of the Commission and the Underwriter. If the Company has elected to rely upon Rule 430A, Rule 430A information previously omitted from the effective Registration Statement pursuant to Rule 430A shall have been transmitted to the Commission for filing pursuant to Rule 424(b) within the prescribed time period and the Company shall have provided evidence satisfactory to the Underwriter of such timely filing, or a post-effective amendment providing such information shall have been promptly filed and declared effective in accordance with the requirements of Rule 430A.

(c) The representations and warranties of the Company contained in this Agreement and in any certificates delivered pursuant to Section 3(d) shall be true and correct when made and on and as of each Closing Date as if made on such date. The Company shall have performed all covenants and agreements and satisfied all the conditions contained in this Agreement required to be performed or satisfied by it at or before such Closing Date.

(d) The Underwriter shall have received on each Closing Date a certificate, addressed to the Underwriter and dated such Closing Date, of the chief executive officer and chief financial officer of the Company to the effect that: (i) the representations, warranties and agreements of the Company in this Agreement were true and correct when made and are true and correct as of such Closing Date; (ii) the Company has performed all covenants and agreements and satisfied all conditions contained herein; (iii) they have carefully examined the Registration Statement, the Prospectus and the General Disclosure Package, and, in their opinion (A) as of the Effective Date the Registration Statement and Prospectus did not include, and as of the Applicable Time, the General Disclosure Package did not include, any untrue statement of a material fact and did not omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, and (B) since the Effective Date no event has occurred which should have been set forth in a supplement or otherwise required an amendment to the Registration Statement, the Statutory Prospectus or the Prospectus; (iv) no stop order suspending the effectiveness of the Registration Statement has been issued and, to their knowledge, no proceedings for that purpose have been instituted or are pending under the Securities Act and (v) there has not occurred any material adverse change in the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company and its subsidiaries considered as a whole.

(e) The Underwriter shall have received: (i) simultaneously with the execution of this Agreement a signed letter from the Auditor addressed to the Underwriter and dated the date of this Agreement, in form and substance reasonably satisfactory to the Underwriter, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement and the General Disclosure Package, and (ii) on each the Closing Date, a signed letter from the Auditor addressed to the Underwriter and dated such Closing Date, in form and substance reasonably satisfactory to the Underwriter containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement and the Prospectus.

(f) The Underwriter shall have received on each Closing Date from Troutman Sanders LLP, corporate counsel for the Company, an opinion and negative assurance statement, addressed to the Underwriter and dated such Closing Date, in form and substance reasonably satisfactory to the Underwriter.

(g) The Underwriter shall have received on each Closing Date from DLA Piper LLP and Bozicevic, Field & Francis LLP, intellectual property counsel for the Company, their opinions, each addressed to the Underwriter and dated such Closing Date, in form and substance reasonably satisfactory to the Underwriter.

(h) The Underwriter shall have received on each Closing Date from Lowenstein Sandler LLP, counsel for the Underwriter, an opinion and negative assurance statement, addressed to the Underwriter and dated such Closing Date, in form and substance reasonably satisfactory to the Underwriter.

(i) All proceedings taken in connection with the sale of the Securities as herein contemplated shall be reasonably satisfactory in form and substance to the Underwriter, and counsel to the Underwriter.

(j) The Underwriter shall have received copies of the Lock-up Agreements executed by each director and executive officer of the Company listed on Schedule I hereto.

(k) The Underwriter shall have received on the Firm Securities Closing Date copies of the executed Pre-Funded Warrants in portable document ("PDF") format.

(l) The Underwriter shall have received on each Closing Date PDF copies of the executed Warrants being sold on such Closing Date

(m) The Company shall have submitted a Notification Form: Listing of Additional Shares with The Nasdaq Capital Market with respect to the Shares, Pre-Funded Warrant Shares and Warrant Shares.

(n) The Underwriter shall be reasonably satisfied that since the respective dates as of which information is given in the Registration Statement, the Statutory Prospectus, the General Disclosure Package and the Prospectus, (i) there shall not have been any material change in the capital stock of the Company or any material change in the indebtedness (other than in the ordinary course of business) of the Company, (ii) except as set forth or contemplated by the Registration Statement, the Statutory Prospectus, the General Disclosure Package or the Prospectus, no material oral or written agreement or other transaction shall have been entered into by the Company that is not in the ordinary course of business or that could reasonably be expected to result in a material reduction in the future earnings of the Company, (iii) no loss or damage (whether or not insured) to the property of the Company shall have been sustained that had or could reasonably be expected to have a Material Adverse Effect, (iv) no legal or governmental action, suit or proceeding affecting the Company or any of its properties that is material to the Company or that affects or could reasonably be expected to affect the transactions contemplated by this Agreement shall have been instituted or threatened and (v) there shall not have been any material change in the assets, properties, condition (financial or otherwise), or in the results of operations, business affairs or business prospects of the Company or its subsidiaries considered as a whole that makes it impractical or inadvisable in the Underwriter's judgment to proceed with the purchase or offering of the Securities as contemplated hereby.

(o) On or prior to the Closing Date, FINRA shall have confirmed that it has not raised any objection with respect to the fairness and reasonableness of the underwriting terms and agreements in connection with the offering of the Securities.

(p) The Company shall have furnished or caused to be furnished to the Underwriter such further certificates or documents as the Underwriter shall have reasonably requested.

4. Covenants and other Agreements of the Company and the Underwriter.

(a) The Company covenants and agrees as follows:

(i) The Company will use its reasonable best efforts to cause the Registration Statement, if not effective at the time of execution of this Agreement, and any amendments thereto, to become effective as promptly as possible. The Company shall prepare the Prospectus in a form approved by the Underwriter and file such Prospectus pursuant to Rule 424(b) under the Securities Act not later than the Commission's close of business on the second business day following the execution and delivery of this Agreement, or, if applicable, such earlier time as may be required by the Rules.

(ii) The Company shall promptly advise the Underwriter in writing (A) when any post-effective amendment to the Registration Statement shall have become effective or any supplement to the Prospectus shall have been filed, (B) of any request by the Commission for any amendment of the Registration Statement or the Prospectus or for any additional information, (C) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any order preventing or suspending the use of any preliminary prospectus or the institution or threatening of any proceeding for that purpose and (D) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Underwritten Securities for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose. The Company shall not file any amendment of the Registration Statement or supplement to the Prospectus unless the Company has furnished the Underwriter a copy for its review prior to filing and shall not file any such proposed amendment or supplement to which the Underwriter reasonably object. The Company shall use its best efforts to prevent the issuance of any such stop order and, if issued, to obtain as soon as possible the withdrawal thereof.

(iii) If, at any time when a prospectus relating to the Securities (or, in lieu thereof, the notice referred to in Rule 173(a) of the Rules) is required to be delivered under the Securities Act, any event occurs as a result of which the Prospectus as then amended or supplemented would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein in the light of the circumstances under which they were made not misleading, or if it shall be necessary to amend or supplement the Prospectus to comply with the Securities Act or the Rules or the Exchange Act and the rules and regulations of the Commission thereunder, the Company promptly shall prepare and file with the Commission, subject to the second sentence of paragraph (ii) of this Section 4(a), an amendment or supplement which shall correct such statement or omission or an amendment which shall effect such compliance.

(iv) The Company shall make generally available to its security holders and to the Underwriter as soon as practicable, but not later than 45 days after the end of the 12-month period beginning at the end of the fiscal quarter of the Company during which the Effective Date occurs (or 90 days if such 12-month period coincides with the Company's fiscal year), an earning statement (which need not be audited) of the Company, covering such 12-month period, which shall satisfy the provisions of Section 11(a) of the Securities Act or Rule 158 of the Rules.

(v) The Company shall furnish to the Underwriter and counsel for the Underwriter, without charge, signed copies of the Registration Statement (including all exhibits thereto and amendments thereof) and to each other Underwriter a copy of the Registration Statement (without exhibits thereto) and all amendments thereof and, so long as delivery of a prospectus by the Underwriter or dealer may be required by the Securities Act or the Rules, as many copies of any Preliminary Prospectus and the Prospectus and any amendments thereof and supplements thereto as the Underwriter may reasonably request. If applicable, the copies of the Registration Statement, any Preliminary Prospectus, and Prospectus and each amendment and supplement thereto furnished to the Underwriter will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(vi) The Company shall cooperate with the Underwriter and their counsel in endeavoring to qualify the Securities for offer and sale in connection with the offering under the laws of such jurisdictions as the Underwriter may designate and shall maintain such qualifications in effect so long as required for the distribution of the Securities; provided, however, that the Company shall not be required in connection therewith, as a condition thereof, to qualify as a foreign corporation or to execute a general consent to service of process in any jurisdiction or subject itself to taxation as doing business in any jurisdiction.

(vii) The Company, during the period when the Prospectus (or in lieu thereof, the notice referred to in Rule 173(a) of the Rules) is required to be delivered under the Securities Act and the Rules or the Exchange Act, will file all reports and other documents required to be filed with the Commission pursuant to Section 13, 14 or 15 of the Exchange Act within the time periods required by the Exchange Act and the regulations promulgated thereunder.

(viii) Without the prior written consent of the Underwriter, for a period of 90 days after the date of this Agreement, the Company shall not issue, sell or register with the Commission (other than on Form S-8 or on any successor form), or otherwise dispose of, directly or indirectly, any equity securities of the Company (or any securities convertible into, exercisable for or exchangeable for equity securities of the Company), except for the issuance of the Securities pursuant to the Registration Statement and the issuance of shares pursuant to the Company's existing stock option plan or bonus plan, or existing warrants or convertible securities as described in the Registration Statement, the Statutory Prospectus and the Prospectus, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities or to extend the term of such securities. The Company represents and warrants that it shall enforce the Lock-Up Agreements and impose stop-transfer restrictions on any sale or other transfer or disposition of securities subject to a Lock-Up Agreement until the end of the applicable period.

(ix) On or before completion of this offering, the Company shall make all filings required under applicable securities laws and by The Nasdaq Capital Market.

(x) Prior to the Closing Date, the Company will issue no press release or other communications directly or indirectly and hold no press conference with respect to the Company, the condition, financial or otherwise, or the earnings, business affairs or business prospects of any of them, or the offering of the Shares without the prior written consent of the Underwriter unless in the judgment of the Company and its counsel, and after notification to the Underwriter, such press release or communication is required by law.

(xi) The Company will apply the net proceeds from the offering of the Underwritten Securities in the manner set forth under "Use of Proceeds" in the Prospectus.

(xii) The Company will promptly notify the Underwriter if the Company ceases to be an Emerging Growth Company at any time prior to the later of (a) completion of the distribution of the Underwritten Securities within the meaning of the Securities Act and (b) completion of the 90-day restricted period referred to in Section 4(a)(viii) hereof.

(xiii) If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a

material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Underwriter and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

(b) The Company agrees to pay, or reimburse if paid by the Underwriter, whether or not the transactions contemplated hereby are consummated or this Agreement is terminated, all costs and expenses incident to the public offering of the Securities and the performance of the obligations of the Company under this Agreement including those relating to: (i) the preparation, printing, reproduction, filing and distribution of the Registration Statement including all exhibits thereto, each Preliminary Prospectus, the Prospectus, all amendments and supplements thereto, and the printing, filing and distribution of this Agreement; (ii) the preparation and delivery of the Shares, Pre-Funded Warrants and Warrants to the Underwriter; (iii) the registration or qualification of the Securities for offer and sale under the securities or Blue Sky laws of the various jurisdictions referred to in Section 4(a)(vi), including the reasonable fees and disbursements of counsel for the Underwriter incurred in connection with such registration and qualification and the preparation, printing, distribution and shipment of preliminary and supplementary Blue Sky memoranda; (iv) the furnishing (including costs of shipping and mailing) to the Underwriter of copies of each Preliminary Prospectus, the Prospectus and all amendments or supplements to the Prospectus, and of the several documents required by this Section 4 to be so furnished, as may be reasonably requested for use in connection with the offering and sale of the Shares, Pre-Funded Warrants and Warrants by the Underwriter or by dealers to whom Shares, Pre-Funded Warrants and Warrants may be sold; (v) the filing fees of FINRA in connection with its review of the terms of the public offering and reasonable fees and disbursements of counsel for the Underwriter in connection with such review; (vi) inclusion of the Shares, Pre-Funded Warrant Shares for listing on The Nasdaq Capital Market; and (vii) all transfer taxes, if any, with respect to the sale and delivery of the Securities by the Company to the Underwriter. The Company will reimburse the Underwriter for its reasonable out-of-pocket costs and expenses incident to this offering and the performance of the obligations of the Underwriter under this Agreement, including its legal fees and disbursements, in connection with the purchase and sale of the Securities contemplated hereby in an amount not to exceed $200,000 (including amounts payable pursuant to clauses (iii) and (v) above). Subject to the provisions of Section 7, the Underwriter agree to pay, whether or not the transactions contemplated hereby are consummated or this Agreement is terminated, all costs and expenses incident to the performance of the obligations of the Underwriter under this Agreement not payable by the Company pursuant to the preceding sentence, including, without limitation, the fees and disbursements of counsel for the Underwriter.

(c) The Company acknowledges and agrees that the Underwriter has acted and is acting solely in the capacity of a principal in an arm's length transaction between the Company, on the one hand, and the Underwriter, on the other hand, with respect to the offering of the Underwritten Securities contemplated hereby (including in connection with determining the terms of the offering) and not as a financial advisor, agent or fiduciary to the Company or any other person. Additionally, the Company acknowledges and agrees that the Underwriter has not and will not advise the Company or any other person as to any legal, tax, investment, accounting or regulatory matters in any jurisdiction. The Company has consulted with its own advisors concerning such matters and shall be responsible for making its own independent investigation and appraisal of the transactions contemplated hereby, and the Underwriter shall have no responsibility or liability to the Company or any other person with respect thereto, whether arising prior to or after the date hereof. Any review by the Underwriter of the Company, the transactions contemplated hereby or other matters relating to such transactions have been and will be performed solely for the benefit of the Underwriter and shall not be on behalf of the Company. The Company agrees that it will not claim that the Underwriter, or any of them, has rendered advisory services of any nature or respect, or owes a fiduciary duty to the company or any other person in connection with any such transaction or the process leading thereto.

(d) The Company represents and agrees that, it has not made and will not make any offer relating to the Underwritten Securities that would constitute an "issuer free writing prospectus," as defined in Rule 433 of the Securities Act, or that would otherwise constitute a "free-writing prospectus," as defined in Rule 405, required to be filed with the Commission.

5. Indemnification.

(a) The Company agrees to indemnify and hold harmless the Underwriter, its officers and employees and each person, if any, who controls the Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all losses, claims, damages and liabilities, joint or several (including any reasonable investigation, legal and other expenses incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted), to which they, or any of them, may become subject under the Securities Act, the Exchange Act or other Federal or state law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in any preliminary prospectus, the Registration Statement, the Statutory Prospectus, the Prospectus, any Written Testing-the-Waters Communication, or in any Blue Sky application or other information or other documents executed by the Company filed in any state or other jurisdiction to qualify any or all of the Securities under the securities laws thereof (any such application, document or information being hereinafter referred to as a "Blue Sky Application") or arise out of or are based upon any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading; provided, however, that such indemnity shall not inure to the benefit of the Underwriter (or any person controlling such Underwriter) on account of any losses, claims, damages or liabilities arising from the sale of the Underwritten Securities to any person by such Underwriter if such untrue statement or omission or alleged untrue statement or omission was made in such preliminary prospectus, the Registration Statement, the Prospectus, the Statutory Prospectus, or such amendment or supplement thereto, any Written Testing-the-Waters Communication, or in any Blue Sky Application in reliance upon and in conformity with the Underwriter Information. This indemnity agreement will be in addition to any liability which the Company may otherwise have.

(b) The Underwriter agrees to indemnify and hold harmless the Company and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, each director of the Company, and each officer of the Company who signs the Registration Statement, against any losses, claims, damages or liabilities (including any reasonable investigation, legal and other expenses incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted) to which such party may become subject, under the Securities Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in any preliminary prospectus, the Registration Statement, the Statutory Prospectus or the Prospectus, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in any Preliminary Prospectus, the Registration Statement, the Statutory Prospectus or the Prospectus or any such amendment or supplement in reliance upon and in conformity with the Underwriter Information; provided, however, that the obligation of the Underwriter to indemnify the Company (including any controlling person, director or officer thereof) shall be limited to the amount of the underwriting discount applicable to the Underwritten Securities purchased by the Underwriter hereunder.

(c) Any party that proposes to assert the right to be indemnified under this Section will, promptly after receipt of notice of commencement of any action, suit or proceeding against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section, notify each such indemnifying party of the commencement of such action, suit or proceeding, enclosing a copy of all papers served. No indemnification provided for in Section 5(a) or 5(b) shall be available to any party who shall fail to give notice as provided in this Section 5(c) if the party to whom notice was not given was unaware of the action, suit or proceeding to which such notice would have related and was prejudiced by the failure to give such notice but the omission so to notify such indemnifying party of any such action, suit or proceeding shall not relieve it from any liability that it may have to any indemnified party for contribution or otherwise than under this Section 5. In case any such action, suit or proceeding shall be brought against any indemnified party and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate in, and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party, and after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof and the approval by the indemnified party of such counsel, the indemnifying party shall not be liable to such indemnified party for any legal or other expenses, except as provided below and except for the reasonable costs of investigation subsequently incurred by such indemnified party in connection with the defense thereof. The indemnified party shall have the right to employ its counsel in any such action, but the fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the employment of counsel by such indemnified party has been authorized in writing by the indemnifying parties, (ii) the indemnified party shall have been advised by counsel that there may be one or more legal defenses available to it which are different from or in addition to those available to the indemnifying party (in which case the indemnifying parties shall not have the right to direct the defense of such action on behalf of the indemnified party) or (iii) the indemnifying parties shall not have employed counsel to assume the defense of such action within a reasonable time after notice of the commencement thereof, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying parties. An indemnifying party shall not be liable for any settlement of any action, suit, and proceeding or claim effected without its written consent, which consent shall not be unreasonably withheld or delayed.

(d) No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is a party or could be named and indemnity was or would be sought hereunder by such indemnified party, unless such settlement, compromise or consent (a) includes an unconditional release of such indemnified party from all liability for claims that are the subject matter of such action, suit or proceeding and (b) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

6. Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in Section 5(a) or 5(b) is due in accordance with its terms but for any reason is unavailable to or insufficient to hold harmless an indemnified party in respect to any losses, liabilities, claims, damages or expenses referred to therein, then each indemnifying party shall contribute to the aggregate losses, liabilities, claims, damages and expenses (including any investigation, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claims asserted, but after deducting any contribution received by any person entitled hereunder to contribution from any person who may be liable for contribution) incurred by such indemnified party, as incurred, in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriter on the other hand from the offering of the Underwritten Securities pursuant to this Agreement or, if such allocation is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to above but also the relative fault of the Company on the one hand and the Underwriter on the other hand in connection with the statements or omissions which resulted in such losses, liabilities, claims, damages or expenses, as well as any other relevant equitable considerations. The Company and the Underwriter agree that it would not be just and equitable if contribution pursuant to this Section 6 were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to above. The aggregate amount of losses, liabilities, claims, damages and expenses incurred by an indemnified party and referred to above shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue or alleged untrue statement or omission or alleged omission. Notwithstanding the provisions of this Section 6, the Underwriter shall not be required to contribute any amount in excess of the underwriting discount actually received by it in connection with the Underwritten Securities purchased by it. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 6, each person, if any, who controls the Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act shall have the same rights to contribution as such Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Section 15 of the Securities Act or Section 20 of the Exchange Act, shall have the same rights to contribution as the Company, as the case may be. Any party entitled to contribution will, promptly after receipt of notice of commencement of any action, suit or proceeding against such party in respect of which a claim for contribution may be made against another party or parties under this Section 6, notify such party or parties from whom contribution may be sought, but the omission so to notify such party or parties from whom contribution may be sought shall not relieve the party or parties from whom contribution may be sought from any other obligation it or they may have hereunder or otherwise than under this Section 6. No party shall be liable for contribution with respect to any action, suit, proceeding or claim settled without its written consent.

7. Termination.

(a) This Agreement may be terminated with respect to the Underwritten Securities to be purchased on a Closing Date by the Underwriter by notifying the Company at any time at or before a Closing Date in the absolute discretion of the Underwriter if: (i) there has occurred any material adverse change in the securities markets or any event, act or occurrence that has materially disrupted, or in the opinion of the Underwriter, will in the future materially disrupt, the securities markets or there shall be such a material adverse change in general financial, political or economic conditions or the effect of international conditions on the financial markets in the United States is such as to make it, in the judgment of the Underwriter, inadvisable or impracticable to market the Underwritten Securities or enforce contracts for the sale of the Underwritten Securities; (ii) there has occurred any outbreak or material escalation of hostilities or acts of terrorism or other calamity or crisis the effect of which on the financial markets of the United States is such as to make it, in the judgment of the Underwriter, inadvisable or impracticable to market the Underwritten Securities or enforce contracts for the sale of the Underwritten Securities; (iii) trading in the Common Stock or any securities of the Company has been suspended or materially limited by the Commission or The Nasdaq Capital Market or trading generally on the New York Stock Exchange, Inc., the NYSE American or The Nasdaq Stock Market has been suspended or materially limited, or minimum or maximum ranges for prices for securities shall have been fixed, or maximum ranges for prices for securities have been required, by any of said exchanges or by such system or by order of the Commission, FINRA, or any other governmental or regulatory authority; or (iv) a banking moratorium has been declared by any state or Federal authority; or (v) in the judgment of the Underwriter, there has been, since the time of execution of this Agreement or since the respective dates as of which information is given in the Prospectus, any material adverse change in the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company and its subsidiaries considered as a whole, whether or not arising in the ordinary course of business.

(b) If this Agreement is terminated pursuant to any of its provisions, the Company shall not be under any liability to the Underwriter, and the Underwriter shall not be under any liability to the Company, except that if this Agreement is terminated by the Underwriter because of any failure, refusal or inability on the part of the Company to comply with the terms or to fulfill any of the conditions of this Agreement, the Company will

reimburse the Underwriter for all out-of-pocket expenses (including the reasonable fees and disbursements of their counsel) incurred by it in connection with the proposed purchase and sale of the Underwritten Securities or in contemplation of performing their obligations hereunder.

8 . Miscellaneous. The respective agreements, representations, warranties, indemnities, rights of contribution and other statements of the Company, and the Underwriter, as set forth in this Agreement or made by or on behalf of them pursuant to this Agreement, shall remain in full force and effect, regardless of any investigation (or any statement as to the results thereof) made by or on behalf of the Underwriter or the Company or any of their respective officers, directors or controlling persons referred to in Sections 5 and 6 hereof, and shall survive delivery of and payment for the Securities. In addition, the provisions of Sections 4(b), 5, 6 and 7(b) shall survive the termination or cancellation of this Agreement.

This Agreement has been and is made for the benefit of the Underwriter, the Company and their respective successors and assigns, and, to the extent expressed herein, for the benefit of persons controlling any of the Underwriter, or the Company, and directors and officers of the Company, and their respective successors and assigns, and no other person shall acquire or have any right under or by virtue of this Agreement. The term "successors and assigns" shall not include any purchaser of Securities from any Underwriter merely because of such purchase. The invalidity or unenforceability of any Section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other Section, paragraph or provision hereof. If any Section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

No amendment or waiver of any provision of this Agreement, nor any consent or approval to any departure therefrom, shall in any event be effective unless and until the same shall be in writing and signed by the Company and the Underwriter.

All notices and communications hereunder shall be in writing and mailed or delivered or by telephone or telegraph if subsequently confirmed in writing, (a) if to the Underwriter, 920 Second Avenue South, Suite 700, Minneapolis, Minnesota 55402, Attention: Michael Townley, Head of Investment Banking, and to Lowenstein Sandler LLP, 1251 Avenue of the Americas, New York, New York 10020 Attention: John D. Hogoboom and (b) if to the Company, to its agent for service as such agent's address appears on the cover page of the Registration Statement with a copy to Troutman Pepper Hamilton Sanders LLP, Union Trust Building, 501 Grant Street, Suite 300, Pittsburgh, Pennsylvania 15219, Attention: Eric D. Kline.

This Agreement and any claim, controversy or dispute arising under or related to this Agreement shall be governed by and construed in accordance with the laws of the State of New York applicable to agreements made and to be performed in such state.

This Agreement may be signed in any number of counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. The headings herein are included for convenience of reference only and are not intended to be part of, or to affect the meaning or interpretation of, this Agreement. This Agreement constitutes the entire agreement of the parties to this Agreement. Notwithstanding anything herein to the contrary, the engagement agreement dated October 3, 2022, as amended, between the Company and the Underwriter, shall continue to be effective and continue to survive and be enforceable by the parties in accordance with its terms, including, but not limited to, Section E thereto.

Please confirm that the foregoing correctly sets forth the agreement among us.

Very truly yours,

ENSYSCE BIOSCIENCES, INC.

By ______________________________
Name: Dr. Lynn Kirkpatrick
Title: President and Chief Executive Officer

Confirmed:

LAKE STREET CAPITAL MARKETS, LLC

By ______________________________
Name:
Title:

[Signature Page to ENSC Underwriting Agreement]

SCHEDULE I

Lock-Up Signatories

Dr. Lynn Kirkpatrick
David Humphrey, CPA
Richard Wright, MBA
Geoffrey Birkett
Linda Pestano, Ph.D.
William Schmidt, Ph.D.
Jeffrey Millard, Ph.D.
Andrew Benton, J.D.
William Chang
Bob Gower, Ph.D.
Adam S. Levin, M.D.
Steve R. Martin

Curtis Rosebraugh, M.D., MPH
Lee Rauch

Exhibit A
FORM OF LOCK-UP AGREEMENT

_____ __, 2022

Lake Street Capital Markets, LLC
920 Second Avenue South, Suite 700
Minneapolis, Minnesota 55402

Re: Public Offering of Ensysce Biosciences, Inc.

Ladies and Gentlemen:

The undersigned executive officer and/or director of Ensysce Biosciences, Inc. (the "Company"), who may be a holder of common stock, par value $0.0001 per share of the Company ("Common Stock"), or rights to acquire Common Stock, understands that you**,** as underwriter, propose to enter into an Underwriting Agreement (the "Underwriting Agreement") with the Company, providing for the public offering (the "Public Offering") of shares of Common Stock and warrants of the Company (the "Securities"). Capitalized terms used herein and not otherwise defined shall have the meanings set forth in the Underwriting Agreement.

In consideration of the Underwriter's agreement to enter into the Underwriting Agreement and to proceed with the Public Offering of the Securities, and for other good and valuable consideration receipt of which is hereby acknowledged, the undersigned hereby agrees, by executing this lock-up agreement (this "Letter Agreement"), for the benefit of the Company and you that, without your prior written consent, the undersigned will not, during the period commencing as of the date hereof and ending 90 days after the date of the final prospectus (the "Prospectus") relating to the Public Offering (the "Lock-up Period"), directly or indirectly (1) offer, pledge, assign, encumber, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, any shares of Common Stock, or any securities convertible into or exercisable or exchangeable for Common Stock (together with the Common Stock, the "Common Securities") owned either of record or beneficially (as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act"), by the undersigned on the date hereof or hereafter acquired or (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise, or publicly announce an intention to do any of the foregoing. In addition, the undersigned agrees that, without your prior written consent, it will not, during the Lock-up Period, make any demand for or exercise any right with respect to, the registration of any Common Securities.

The foregoing restrictions shall not apply to:

1. transfers of Common Securities as a gift or gifts;

2. transfers of Common Securities to any trust for the direct or indirect benefit of the undersigned or the immediate family (as defined below) of the undersigned;

3. if the undersigned is, or otherwise holds any Common Securities through, a corporation, partnership, limited liability company, trust or other business entity (1) transfers without consideration to another corporation, partnership, limited liability company, trust or other business entity that is a direct or indirect affiliate (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) of the undersigned or (2) distributions of Common Securities to limited partners, limited liability company members or stockholders of the undersigned;

4. transfers of Common Securities by testate or intestate succession;

5. transfers of Common Securities by operation of law;

6. the transfer of Common Securities pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction that is approved by the Board of Directors of the Company and made to all securityholders of the Company involving a Change of Control;

7. the sale of the Securities purchased by the undersigned in the Public Offering;

provided however, in the case of clauses (1)-(5), that the transferee agrees in writing with the Underwriter to be bound by the terms of this Letter Agreement, and in the case of clauses (1)-(5), no filing by any party under Section 16(a) of the Exchange Act shall be required or shall be made voluntarily in connection with such transfer or sale.

For purposes of this Letter Agreement, "immediate family" shall mean any relationship by blood, marriage, domestic partnership or adoption, not more remote than first cousin and "Change of Control" shall mean the transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons (other than the Underwriter pursuant to the Public Offering), of the Company's voting securities if, after such transfer, such person or group of affiliated persons would hold more than 50% of the outstanding voting securities of the Company (or the surviving entity).

In addition, the foregoing restrictions shall not apply to (i) the exercise of stock options granted pursuant to the Company's equity incentive plans in place as of the date of the Prospectus (including by way of "net" or "cashless" exercise and/or the sale of the Common Stock received upon such exercise to the Company to cover withholding tax obligations in connection with such exercise), (ii) the vesting or settlement of restricted stock units granted pursuant to the Company's equity incentive plans in place as of the date of the Prospectus (including the sale of the Common Stock received upon such vesting or settlement to cover withholding tax obligations in connection with such vesting or settlement); *provided, that,* in the cases of clauses (i) and (ii) such restrictions shall apply to any of the undersigned's Common Securities issued upon such exercise or vesting or settlement, or (iii) sales under, any contract, instruction or plan that the undersigned established prior to the date hereof and that satisfies all of the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act.

In furtherance of the foregoing, the Company and its duly appointed transfer agent and registrar are hereby authorized to decline to make any transfer of Common Securities if such transfer would constitute a violation or breach of this Letter Agreement.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Letter Agreement. All authority herein conferred or agreed to be conferred and any obligations of the undersigned shall be binding upon the successors, assigns, heirs or personal representatives of the undersigned.

The undersigned understands that this Letter Agreement will terminate and the undersigned shall be released form all obligations hereunder if (i) the Underwriting Agreement does not become effective by December 31, 2022, (ii) the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Common Stock to be sold thereunder and (iii) the Company notifies the Underwriter that it does not intend to proceed with the Public Offering.

The undersigned, whether or not participating in the Public Offering, understands that the Underwriter is entering into the Underwriting Agreement and proceeding with the Public Offering in reliance upon this Letter Agreement.

[Signature page follows]

This Letter Agreement shall be governed by and construed in accordance with the laws of the State of New York.

Very truly yours,

____
Printed Name of Stockholder

By: __________________________________

Exhibit B

FORM OF PRE-FUNDED WARRANT

Exhibit C

FORM OF SERIES A WARRANT

Exhibit D

FORM OF SERIES B WARRANT

Exhibit 4.10

[SERIES A]/[SERIES B] COMMON STOCK PURCHASE WARRANT

ENSYSCE BIOSCIENCES, INC.

Warrant Shares: ___________ Issue Date: [●], 2022

Initial Exercise Date: [●], 2022

THIS [SERIES A]/[SERIES B] COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received______________ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after [●], 2022 (the "Initial Exercise Date") and on or prior to 5:00 p.m. (New York City time) on [●][1] (the "Termination Date") but not thereafter, to subscribe for and purchase from Ensysce Biosciences, Inc., a Delaware corporation (the "Company"), up to ______________ shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the reasonable fees and expenses of which shall be paid by the Company.

[1] For Series A Warrants, insert the date that is the 5 year anniversary of the Initial Exercise Date, provided that, if such date is not a Trading Day, insert the immediately following Trading Day. For Series B Warrants, insert date that is the 6 month anniversary of the Initial Exercise Date, provided that, if such date is not a Trading Day, insert the immediately following Trading Day.

"Board of Directors" means the board of directors of the Company.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Registration Statement" means the effective registration statement on Form S-1 filed with Commission (File No. 333-268038), including all information, documents and exhibits filed with or incorporated by reference into such registration statement, as amended from time to time, which registers the sale the Warrants and the Warrant Shares, among others, and includes any Rule 462(b) Registration Statement.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Subsidiaries" means the subsidiaries of the Company set forth on Exhibit 21.1 to the Registration Statement and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

"Trading Day" means a day on which the Common Stock is traded on a Trading Market.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

"Transfer Agent" means Continental Stock Transfer & Trust Company, the current transfer agent of the Company, with a mailing address of 1 State St 30th floor, New York, NY 10004, and any successor transfer agent of the Company.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a

majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the reasonable fees and expenses of which shall be paid by the Company.

"Warrants" means this Warrant and other [Series A]/[Series B] Common Stock purchase warrants issued by the Company pursuant to the Registration Statement.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form attached hereto as Annex A (the "Notice of Exercise"). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank, in either case in immediately available funds, unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. The Company shall have no obligation to inquire with respect to or otherwise confirm the authenticity of the signature(s) contained on any Notice of Exercise nor the authority of the person so executing such Notice of Exercise. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Trading Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per share of Common Stock under this Warrant shall be $[●], subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares by the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. ("Bloomberg") as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company's transfer agent is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that the Company shall have received payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay, beginning one Trading Day after the Warrant Share Delivery Date, to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), $10 per Trading Day (increasing to $20 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of the delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares remaining available under this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise by delivering written notice to the Company at any time prior to the delivery of such Warrant Shares (in which case any liquidated damages payable under Section 2(d)(i) shall no longer be payable).

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including reasonable and customary brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the assignment form attached hereto as Annex B (the "Assignment Form") duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Beneficial Ownership Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith and the calculations required under this Section 2(e). To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written request of a Holder, the Company shall within one (1) Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this Section 2(e) shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this Section 2(e) (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations

contained in this Section 2(e) shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time while this Warrant is outstanding the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation); provided, that such Purchase Right shall terminate on, and shall not be held in abeyance for any period subsequent to the Termination Date.

c) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation); provided, that such Purchase Right shall terminate on, and shall not be held in abeyance for any period subsequent to the Termination Date.

d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company (and all of its Subsidiaries, taken as a whole), directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person (other than for the purpose of changing the Company's name and/or the jurisdiction of incorporation of the Company or a holding company for the Company), (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding shares of Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires securities representing more than 50% of the aggregate voting power, including the power to vote on the election of directors of the Company, of the issued and outstanding equity securities of the Company (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction (other than (x) any stock split or reverse stock split, (y) any transaction effected solely for the purpose of changing the jurisdiction of incorporation of the Company, or (z) any holding company reorganization or parent-subsidiary merger not requiring stockholder approval pursuant to Sections 251(g) or 253 of the Delaware General Corporation Law (or any successor provisions thereof)), the Company or any Successor Entity (as defined below) shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value (as defined below) of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, if the Fundamental Transaction is not within the Company's control, including not approved by the Company's Board of Directors, Holder shall only be entitled to receive from the Company or any Successor Entity, as of the date of consummation of such Fundamental Transaction, the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of this Warrant, that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the Successor Entity (which Successor Entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction. "Black Scholes Value" means the value of this Warrant based on the Black Scholes Option Pricing Model obtained from

the "OV" function on Bloomberg determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the 100 day volatility obtained from the HVT function on Bloomberg (determined utilizing a 365-day annualization factor) as of the Trading Day immediately following the public announcement of the applicable Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the greater of (i) the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (ii) the highest VWAP during the period beginning on the Trading Day immediately preceding the announcement of the applicable Fundamental Transaction (or the consummation of the applicable Fundamental Transaction, if earlier) and ending on the Trading Day of the Holder's request pursuant to this Section 3(d) and (D) a remaining option time equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds within five (5) Trading Days of the Holder's election (or, if later, on the effective date of the Fundamental Transaction). The Company shall require any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(d) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein.

e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (and all of its Subsidiaries, taken as a whole) is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by email to the Holder at its last email or other address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers a duly executed Assignment Form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose

of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a "cashless exercise" pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then such action may be taken or such right may be exercised on the next succeeding Trading Day.

d) Authorized Shares.

The Company covenants that during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. The Company and, by accepting this Warrant, the Holder each agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against the Company or the Holder or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. The Company and, by accepting this Warrant, the Holder each hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. The Company and, by accepting this Warrant, the Holder each hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to it at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If the Company or the Holder shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holder hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by email or sent by a nationally recognized overnight courier service, addressed to the Company, at 7946 Ivanhoe Avenue, Suite 201 , La Jolla, California 92037, Attention: David Humphrey, CFO, email address: dhumphrey@ensysce.com, or such other email address or address as the Company may specify for such purposes by notice to the Holder. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by email, or sent by a nationally recognized overnight courier service addressed to the Holder at the email address or address of the Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via email at the email address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via email at the email address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided by the Company hereunder constitutes, or contains, material, non-public information regarding the Company or any subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by such Holder.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the holders of at least a majority of the Common Stock issuable upon the exercise of the then outstanding Warrants (determined without giving effect to Section 2(e) of the Warrants); provided such modification, amendment or waiver applies to all of the then outstanding Warrants.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

o) Electronic Signatures. Electronically scanned and transmitted signatures, including by email attachment, shall be deemed originals for all purposes of this Warrant.

****

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

ENSYSCE BIOSCIENCES, INC.

By: ______________________________
Name: Dr. Lynn Kirkpatrick
Title: President and Chief Executive Officer

Annex A

NOTICE OF EXERCISE

TO: **ENSYSCE BIOSCIENCES, INC.**

(1) The undersigned hereby elects to purchase ________ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

[ ] in lawful money of the United States; or

[ ] if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

____

The Warrant Shares shall be delivered to the following DWAC Account Number:

____

____

____

[SIGNATURE OF HOLDER]

Name of Investing Entity: ____
Signature of Authorized Signatory of Investing Entity: ____
Name of Authorized Signatory: ____
Title of Authorized Signatory: ____
Date: ____

Annex B

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to exercise the Warrant to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: ______________________________________
(Please Print)

Address: ______________________________________
(Please Print)

Phone Number: ______________________________________

Email Address: ______________________________________

Dated: _______________ __, ______

Holder's Signature:_______________________________

Holder's Address:_______________________________

Exhibit 4.11

PRE-FUNDED COMMON STOCK PURCHASE WARRANT

ENSYSCE BIOSCIENCES, INC.

Warrant Shares: _______ Issue Date: [●], 2022

Initial Exercise Date: [●], 2022

THIS PRE-FUNDED COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, ______________ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date set forth above (the "Initial Exercise Date") and until this Warrant is exercised in full (the "Termination Date") but not thereafter, to subscribe for and purchase from Ensysce Biosciences, Inc., a Delaware corporation (the "Company"), up to ______________ shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the reasonable fees and expenses of which shall be paid by the Company.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Registration Statement" means the effective registration statement on Form S-1 filed with Commission (File No. 333-268038), including all information, documents and exhibits filed with or incorporated by reference into such registration statement, as amended from time to time, which registers the sale the Warrants and the Warrant Shares, among others, and includes any Rule 462(b) Registration Statement.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Subsidiaries" means the subsidiaries of the Company set forth on Exhibit 21.1 to the Registration Statement and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

"Trading Day" means a day on which the Common Stock is traded on a Trading Market.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

"Transfer Agent" means Continental Stock Transfer & Trust Company, the current transfer agent of the Company, with a mailing address of 1 State St 30th floor, New York, NY 10004, and any successor transfer agent of the Company.

"Underwriting Agreement" means that certain Underwriting Agreement, dated as of [●], 2022 by and between the Company and Lake Street Capital Markets, LLC.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the reasonable fees and expenses of which shall be paid by the Company.

"Warrants" means this Warrant and other pre-funded Common Stock purchase warrants issued by the Company pursuant to the Registration Statement.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form attached hereto as Annex A (the "Notice of Exercise"). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank, in either case in immediately available funds, unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. The Company shall have no obligation to inquire with respect to or otherwise confirm the authenticity of the signature(s) contained on any Notice of Exercise nor the authority of the person so executing such Notice of Exercise. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Trading Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The aggregate exercise price of this Warrant, except for a nominal exercise price of $0.0001 per Warrant Share, was pre-funded to the Company on or prior to the Initial Exercise Date and, consequently, no additional consideration (other than the nominal exercise price of $0.0001 per Warrant Share) shall be required to be paid by the Holder to any Person to effect any exercise of this Warrant. The Holder shall not be entitled to the return or refund of all, or any portion, of such pre-paid aggregate exercise price under any circumstance or for any reason whatsoever. The remaining unpaid exercise price per share of Common Stock under this Warrant shall be $0.0001, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. This Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. ("Bloomberg") as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company's transfer agent is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that the Company shall have received payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay, beginning one Trading Day after the Warrant Share Delivery Date, to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), $10 per Trading Day (increasing to $20 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of the delivery of the Notice of Exercise. Notwithstanding the foregoing, with respect to any Notice(s) of Exercise delivered on or prior to 12:00 p.m. (New York City time) on the Initial Exercise Date, which may be delivered at any time after the time of execution of the Underwriting Agreement, the Company agrees to deliver the Warrant Shares subject to such notice(s) by 4:00 p.m. (New York City time) on the Initial Exercise Date and the Initial Exercise Date shall be the Warrant Share Delivery Date for purposes hereunder, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received by such Warrant Share Delivery Date.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares remaining available under this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise by delivering written notice to the Company at any time prior to the delivery of such Warrant Shares (in which case any liquidated damages payable under Section 2(d)(i) shall no longer be payable).

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including reasonable and customary brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the assignment form attached hereto as Annex B (the "Assignment Form") duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Beneficial Ownership Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith and the calculations required under this Section 2(e). To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written request of a Holder, the Company shall within one (1) Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be [4.99%]/[9.99%] of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this Section 2(e) shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this Section 2(e) (or any portion hereof) which may be defective or inconsistent with the

intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this Section 2(e) shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time while this Warrant is outstanding the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation); provided, that such Purchase Right shall terminate on, and shall not be held in abeyance for any period subsequent to the Termination Date.

c) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation); provided, that such Purchase Right shall terminate on, and shall not be held in abeyance for any period subsequent to the Termination Date.

d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company (and all of its Subsidiaries, taken as a whole), directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person (other than for the purpose of changing the Company's name and/or the jurisdiction of incorporation of the Company or a holding company for the Company), (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding shares of Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires securities representing more than 50% of the aggregate voting power, including the power to vote on the election of directors of the Company, of the issued and outstanding equity securities of the Company (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall require any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(d) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein.

e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (and all of its Subsidiaries, taken as a whole) is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by email to the Holder at its last email or other address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

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Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers a duly executed Assignment Form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

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Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a "cashless exercise" pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then such action may be taken or such right may be exercised on the next succeeding Trading Day.

d) Authorized Shares.

The Company covenants that during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares

upon the exercise of the purchase rights under this Warrant. The Company will take such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. The Company and, by accepting this Warrant, the Holder each agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against the Company or the Holder or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. The Company and, by accepting this Warrant, the Holder each hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. The Company and, by accepting this Warrant, the Holder each hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If the Company or the Holder shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holder hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by email or sent by a nationally recognized overnight courier service, addressed to the Company, at 7946 Ivanhoe Avenue, Suite 201, La Jolla, California 92037, Attention: David Humphrey, CFO, email address: dhumphrey@ensysce.com, or such other email address or address as the Company may specify for such purposes by notice to the Holder. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by email, or sent by a nationally recognized overnight courier service addressed to the Holder at the email address or address of the Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via email at the email address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via email at the email address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided by the Company hereunder constitutes, or contains, material, non-public information regarding the Company or any subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by such Holder.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the holders of at least a majority of the Common Stock issuable upon the exercise of the then outstanding Warrants (determined without giving effect to Section 2(e) of the Warrants); provided such modification, amendment or waiver applies to all of the then outstanding Warrants.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

o) Electronic Signatures. Electronically scanned and transmitted signatures, including by email attachment, shall be deemed originals for all purposes of this Warrant.

****

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

ENSYSCE BIOSCIENCES, INC.

By: ______________________________
Name: Dr. Lynn Kirkpatrick
Title: President and Chief Executive Officer

Annex A

NOTICE OF EXERCISE

TO: **ENSYSCE BIOSCIENCES, INC.**

(1) The undersigned hereby elects to purchase ________ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

☐ in lawful money of the United States; or

☐ if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

____

The Warrant Shares shall be delivered to the following DWAC Account Number:

____

____

____

[SIGNATURE OF HOLDER]

Name of Investing Entity: ______________________________
Signature of Authorized Signatory of Investing Entity: ______________________________
Name of Authorized Signatory: ______________________________
Title of Authorized Signatory: ______________________________
Date: ______________________________

Annex B

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to exercise the Warrant to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: ______________________________
(Please Print)

Address: ______________________________

(Please Print)

Phone Number: ______________________________________

Email Address: ______________________________________

Dated: _______________ __, ______
Holder’s Signature:_______________________
Holder’s Address:________________________

Exhibit 5.1

Troutman Pepper Hamilton Sanders LLP
Union Trust Building, 501 Grant Street, Suite 300
Pittsburgh, PA 15219-4429

troutman.com

November 16, 2022

Ensysce Biosciences, Inc.
7946 Ivanhoe Avenue, Suite 201
La Jolla, California 92037

Ladies and Gentlemen:

Re: Securities Registered under Registration Statement on Form S-1

Ladies and Gentlemen:

We have acted as counsel to Ensysce Biosciences, Inc., a Delaware corporation (the "Company"), in connection with the registration statement on Form S-1 (as amended, the "Registration Statement") filed with the Securities and Exchange Commission (the "SEC"), and a related prospectus included in the Registration Statement (the "Prospectus"), on October 28, 2022 and amended on November 16, 2022, relating to the registration under the Securities Act of 1933, as amended (the "Act"), by the Company of a proposed maximum offering of up to (i) an aggregate of either (A) 5,265,567 shares (the "Shares") of common stock, $0.0001 par value per share (the "Common Stock"), of the Company or (B) pre-funded warrants (the "Prefunded Warrants") to purchase 5,265,567 shares of Common Stock (the "Prefunded Warrant Shares") in lieu of such Shares, (ii) warrants of five-year duration (the "Series A Warrants") to purchase 5,265,567 shares of Common Stock (the "Series A Warrant Shares") and (iii) warrants of six-month duration (the "Series B Warrants") to purchase 5,265,567 shares of Common Stock (the "Series B Warrant Shares" and, collectively with the Shares, the Prefunded Warrants, the Prefunded Warrant Shares, the Series A Warrants, the Series A Warrant Shares and the Series B Warrants, the "Securities"), including Shares, Series A Warrants and Series B Warrants that may be sold by the Company pursuant to the exercise of an over-allotment option granted to the Underwriter (as defined below). The Securities are being sold to the underwriter named in (the "Underwriter"), and pursuant to, an underwriting agreement between the Company and such underwriter (the "Underwriting Agreement).

This opinion is being furnished in accordance with the requirements of Item 16(a) of Form S-1 and Item 601(b)(5)(i) of Regulation S-K.

For purposes of the opinions we express below, we have examined the originals or copies, certified or otherwise identified, of (i) the Registration Statement, (ii) the Company's Third Amended and Restated Certificate of Incorporation and the Amended and Restated Bylaws of the Company, each as amended and/or restated to date, (iii) the Underwriting Agreement, and (iv) such other instruments and documents as we considered appropriate for purposes of the opinions hereafter expressed.

In connection with

rendering the opinions set forth below, we have assumed without verification (i) the authenticity of all documents submitted to us as originals, (ii) the conformity to the originals of all documents submitted as certified, photostatic or electronic copies and the authenticity of the originals thereof, (iii) the legal capacity of natural persons, (iv) the genuineness of signatures not witnessed by us, including electronic signatures, (v) the due authorization, execution and delivery of all documents by all parties, other than the Company, and the validity, binding effect and enforceability thereof, and (vi) the truth, accuracy and completeness of the information, representations and warranties contained in the records, documents, instruments and certificates we have reviewed.

Troutman Pepper Hamilton Sanders LLP
Union Trust Building, 501 Grant Street, Suite 300
Pittsburgh, PA 15219-4429

troutman.com

With respect to the Series A Warrant Shares, the Series B Warrant Shares, and the Prefunded Warrant Shares, we express no opinion to the extent that, notwithstanding the Company's current reservation of shares of Common Stock, future issuances of securities of the Company and/or anti-dilution adjustments to outstanding securities of the Company may cause the exercise of the Series A Warrants, the Series B Warrants and the Prefunded Warrants for more shares of Common Stock than the number that then remain authorized but unissued. Further, we have assumed the exercise prices of the Series A Warrants, the Series B Warrants, and the Prefunded Warrants will not be adjusted to an amount below the par value per share of the shares of Common Stock.

As to factual matters, we have relied upon the documents furnished to us by the Company, the certificates and other comparable documents of officers and representatives of the Company, statements made to us in discussions with the Company's management and certificates of public officials, without independent verification of their accuracy.

We are opining herein as to the General Corporation Law of the State of Delaware and we express no opinion with respect to any other laws. We are not opining as to the applicability thereto, or the effect thereon, of the laws of any other jurisdiction or, in the case of Delaware, any other laws, or as to matters of municipal law or the laws of any local agencies within any states (including "blue sky" or other state securities laws).

With regard to our opinion concerning the Series A Warrants, the Series B Warrants and the Prefunded Warrants constituting valid and binding obligations of the Company:

(i) Our opinion is subject to, and may be limited by, (a) applicable bankruptcy, reorganization, insolvency, moratorium, fraudulent conveyance, debtor and creditor, and similar laws which relate to or affect creditors' rights generally, and (b) general principles of equity (including, without limitation, concepts of materiality, reasonableness, good faith and fair dealing) regardless of whether considered in a proceeding in equity or at law.

(ii) Our opinion is subject to the qualification that the availability of specific performance, an injunction or other equitable remedies is subject to the discretion of the court before which the request is brought.

(iii) We express no opinion as to any provision of the Series A Warrants, the Series B Warrants and the Prefunded Warrants that: (a) provides for liquidated damages, buy-in damages, monetary penalties, prepayment or make-whole payments or other economic remedies to the extent such provisions may constitute unlawful penalties, (b) relates to advance waivers of claims, defenses, rights granted by law, or notice, opportunity for hearing, evidentiary requirements, statutes of limitations, trial by jury, or procedural rights, (c) restricts non-written modifications and waivers, (d) provides for the payment of legal and other professional fees where such payment is contrary to law or

public policy, (e) relates to exclusivity, election or accumulation of rights or remedies, (f) authorizes or validates conclusive or discretionary determinations, or (g) provides that provisions of the Underwriting Agreement, Series A Warrants, the Series B Warrants and the Prefunded Warrants are severable to the extent an essential part of the agreed exchange is determined to be invalid and unenforceable.

(iv) We express no opinion as to whether a state court outside of the State of New York or a federal court of the United States would give effect to the choice of New York law provided for in the Underwriting Agreement, the Series A Warrants, the Series B Warrants and the Prefunded Warrants. We also express no opinion as to compliance with any federal securities laws.

Troutman Pepper Hamilton Sanders LLP
Union Trust Building, 501 Grant Street, Suite 300
Pittsburgh, PA 15219-4429

troutman.com

Based on the foregoing and in reliance thereon, and subject to the limitations, qualifications, assumptions, exceptions and other matters set forth herein, we are of the opinion that:

(1) The Shares have been duly authorized and, upon issuance and delivery against payment therefor in accordance with the terms of the Underwriting Agreement, the Shares will be validly issued, fully paid and non-assessable.

(2) The Series A Warrants, the Series B Warrants and the Prefunded Warrants have been duly authorized and, when issued, delivered and paid for in accordance with the terms of the Underwriting Agreement, will be valid and binding obligations of the Company.

(3) The Series A Warrant Shares have been duly authorized, and when and if issued upon exercise of the Series A Warrants in accordance with the terms of the Series A Warrants, will be validly issued, fully paid and non-assessable. The Series B Warrant Shares have been duly authorized, and when and if issued upon exercise of the Series B Warrants in accordance with the terms of the Series B Warrants, will be validly issued, fully paid and non-assessable. The Prefunded Warrant Shares, have been duly authorized, and when and if issued upon exercise of the Prefunded Warrants in accordance with the terms of the Prefunded Warrants, will be validly issued, fully paid and non-assessable.

Our opinion is as of the date hereof and we have no responsibility to update this opinion for events and circumstances occurring after the date hereof or as to facts relating to prior events that are subsequently brought to our attention and we disavow any undertaking to advise you of any changes in law.

We hereby consent to the filing of this opinion letter as Exhibit 5.1 to the Registration Statement and to the use of our name under the caption "Legal Matters" in the Registration Statement and in the Prospectus forming a part thereof and any supplement thereto. In giving this consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the SEC promulgated thereunder.

Very truly yours,

/s/ Troutman Pepper Hamilton Sanders LLP

TROUTMAN PEPPER HAMILTON SANDERS LLP

Certain identified information has been excluded from this Exhibit 10.24 because it is both not material and is the type that the registrant treats as private or confidential. Brackets have been inserted where such information was omitted.

March 29, 2022

Lynn Kirkpatrick
Chief Executive Office
Ensysce Biosciences, Inc.
3210 Merryfield Row
San Diego, CA 92121

Dear Lynn,

Thank you for your interest in Johnson Matthey. As a follow-up to your recent request, we are pleased to provide Ensysce Biosciences with this proposal for GMP manufacture of PF614.

Please note that this proposal is based on technical information provided by Ensysce Biosciences as part of your request for proposal. If additional information becomes available that may modify our assumptions, we are happy to discuss them with you in detail as they may impact this proposal.

Please contact me if I can provide additional information or be of additional service. We are excited about the opportunity to support your chemistry service needs and look forward to your feedback on this proposal.

Kind Regards,

/s/ Laura Milbrandt

Laura Milbrandt
Business Development Manager
Johnson Matthey
25 Patton Road
Devens, MA 01434

Proposal for GMP manufacture of PF614 for Ensysce Biosciences, Inc.

Proposal Date: March 29, 2022

Proposal Number: 202202-31203

Johnson Matthey Pharmaceutical Materials, Inc. d/b/a Johnson Matthey Pharma Services (referred to as “JM” hereinafter), is pleased to provide Ensysce Biosciences, Inc. with this proposal for GMP manufacture of PF614.

All work specified in this proposal is subject to the JM Terms and Conditions of Sale attached hereto (“Terms and Conditions”).

The table below provides a high-level summary of the price and timeline proposed with additional details provided in the Scope of Work.

Proposal No: 202202-31203

Stage #	Stage Title	Fixed Fee*	Timeline**
1	cGMP Manufacture of targeted quantity of [ ] Kg PF614 *(subject to revision)*	$[ ]	[ ] months

*Includes all direct materials.
** Timeline is from commencement of work on the stage and follows receipt of all materials.

JM will use commercially reasonable efforts to achieve the deliverables as outlined in this proposal. This estimate is based on a specific scope of work that was developed using technical information provided by Ensysce Biosciences. Project objectives or technical details may differ from those assumed in this estimate. If a significant difference occurs from the originally proposed scope of work or with the actual technical details from those assumed, JM will assess the impact of such a change and inform Ensysce Biosciences. JM and Ensysce Biosciences will promptly and in good faith develop and agree to a modified project plan to ensure that project delays are avoided or minimized. If these changes result in additional cost, Ensysce Biosciences must authorize the additional cost in writing prior to implementation.

At any time at or after the execution of this proposal, Ensysce Biosciences and JM may mutually agree from time to time to change or expand the Scope of Work agreed upon herein. With respect to each change to the Scope of Work, Ensysce Biosciences and JM shall prepare and execute a change order (“Change Order”), substantially in the form attached as Exhibit A hereto, describing the changes to the Scope of Work, any changes to the pricing, and any changes to the timeline for completion of the revised Scope of Work. Except as may be specified in writing in a Change Order, all work conducted under a Change Order shall be subject to the Terms & Conditions.

JM will schedule resources and order materials upon acceptance of this proposal. Scheduling is contingent on prevailing staff commitments, raw material, and equipment availability. Ensysce Biosciences will be notified of the expected start date as soon as is practical. JM will appoint a project leader to oversee the work and serve as the primary technical liaison with Ensysce Biosciences. Project updates will be submitted weekly and conference calls will be arranged on a frequency agreed upon by both parties.

JM will provide a list of all project materials (including, but not limited to, Deliverables as well as starting materials and/or equipment) to Ensysce Biosciences within thirty (30) days after project completion. Within fifteen (15) days after receipt of such project materials list, Ensysce Biosciences shall provide JM with shipping or disposal instructions for all such project materials. JM may dispose of any excess purchased starting materials and/or equipment (e.g. reagents, solvents, catalyst) remaining at the end of the project unless Ensysce Biosciences has provided shipping instructions within the fifteen (15) day period. All shipping and disposal fees related to project materials shall be invoiced in the month they are incurred and shall be in addition to project fees as outlined in this proposal. In no event shall JM be liable for any project materials remaining at JM beyond sixty (60) days following project completion.

Notwithstanding anything to the contrary, all financial terms for this proposal are subject to revision following a review of Ensysce Biosciences by JM's credit department. Ensysce Biosciences will be invoiced a deposit of 80% of this proposal. Final payment in full is required prior to shipment of the material. Invoices for fixed fee work are issued upon completion of the deliverables. Notwithstanding any of the foregoing, remaining deposit amounts may be applied by JM against any of Ensysce Biosciences' past due payments under this or any other proposal. Invoices for deposits are due upon receipt. All other Invoices are payable within thirty (30) days from the date of issuance. Unless specified differently in writing, all sales are F.C.A. (Seller's shipping point).

Postponement or Cancellation: Ensysce Biosciences shall notify JM, in writing, in advance of any desired change to the planned production schedule in Stage 1, including postponement or cancellation. Ensysce Biosciences will pay JM for any and all work performed as of the time of such notice and compensate JM for all non-recoverable and non-cancellable direct expenses related to this Project that have been ordered in advance of commencement of work for this Project, including any relevant shipping and disposal costs. JM will make reasonable commercial effort to fill unused capacity left by the cancellation or postponement of this work. In addition to the aforementioned payment of fees for work performed and expenses incurred, Ensysce Biosciences will compensate JM based on the schedule below:

Compensation Schedule – Postponement or Cancellation *(Devens)*

Calendar Days Prior to Manufacture Start Date	Price*	
91-120	$	[ ] (50%)
61-90	$	[ ] (75%)
60 or less	$	[ ] (100%)

*This Price is per lot of PF614 and is inclusive of direct expenses except where noted above. Credit will be given for any direct expenses not purchased or incurred by JM and raw materials that can be returned to vendor or otherwise reasonably useable by JM for another related or unrelated project. Further consideration/credit for these fees will be considered by JM in the event that some or all of the idle capacity is filled successfully by JM with other business.

For projects that are postponed, JM and Ensysce Biosciences will negotiate in good faith a fee to compensate JM for idle capacity; provided, however, that any postponement by Ensysce Biosciences of a Project for longer than two (2) months beyond the initially scheduled commencement date shall be deemed a cancellation of the project and the above Compensation Schedule(s) for cancellation shall be applicable thereto. In the event of any postponement, upon Ensysce Biosciences' notice to JM for the recommencement of the project, scheduling of the new commencement date is contingent on then-prevailing staff commitments, raw material, and equipment availability. Ensysce Biosciences will be notified of the expected start date as soon as is practical.

This proposal is valid for sixty (60) days from the preparation date.

Scheme

[

]

SCOPE OF WORK

JM will use commercially reasonable efforts to meet all milestones as outlined in this proposal. This proposal is based on technical information provided by Ensysce Biosciences as part of the request for proposal dated 02/08/22 and other available technical information within the public literature and available at JM.

Assumptions

1. The work in this proposal will be conducted by JM in Devens, MA.

2. The scope of work described herein is based on the process from the previous JM manufacture campaign of PF614 for Ensysce Biosciences and from the ongoing work under proposal # 202104-29506. The yields used in this proposal are summarized in the Table below:

Process step	Yield used in this proposal	Comments
Oxycodone base	[ ]	Expected Procurement quota of Oxycodone base is [ ] Kg

4346.A non-isolated	[ ]	Used to calculate input of RSM Compound F
Compound F to PF614 (4346.D)	[ ]	Executed yield for 4346.D.20.1 was [ ]

Based on the above yields, on the expected procurement quota (expected for [ ]Kg of Oxycodone) and the maximum volumetric occupancy of the kilo lab reactors, it is estimated that approximately [ ] Kg of Oxycodone.HCl (corresponding to approximately [ ] Kg of Oxycodone base) and approximately [ ] Kg of Compound F will be required for the targeted preparation of [ ] Kg of PF614.

3. Stage 1 of this proposal is subject to revision based on the successful manufacture of the Stage 4 GMP kilo lab batch as per proposal # 202104-29506 and related change orders.
4. If JM is able to procure Oxycodone base to support the work in this proposal, then a Change Order will apply.
5. The deliverables under this proposal may be the subject of third-party patents and patent applications. It is Ensysce Biosciences' responsibility to ensure freedom to operate for any use of the deliverables and no representation or warranty (express or implied) is given in this respect.
6. Oxycodone.HCl, Oxycodone base, all opioid intermediates and PF614 are Schedule 2 Controlled Substances. Procurement quota will be required in order to acquire Oxycodone.HCl for Stage 1. The scheduling of this stage is subject to approval of Procurement Quota by the DEA. Assumed procurement quota is [ ] Kg.
7. All non-opioid compounds including Compound F are not controlled substances.
8. Oxycodone base and [ ] will be considered the regulatory starting materials.
9. Intermediates 4346.A and 4346.B will be non-isolated.
10. Chiral purity will be determined upon release of [ ]and no chiral method for the API is required.

11. Microbial testing for PF614 will be conducted at a qualified contract laboratory.
12. PF614 and its intermediates are considered non-potent (Category 2 out of 4 on a SafeBridge scale, JM Control Band 3 out of 6), however, since Oxycodone has narcotic effects and is acutely toxic by oral and inhalation routes, Oxycodone and its analogues will be handled using appropriate laboratory techniques.

Stage 1: **cGMP Manufacture of Targeted quantity of [ ] Kg PF614**

The following is an estimate of the work to be performed by JM under this mutually binding Proposal, subject to revision (such as price and timing) upon completion of the work in proposal # 202104-29506 (and related Change Orders).

JM will manufacture approximately [ ] Kg of Oxycodone base under non-GMP conditions in the kilo lab in Devens, MA. The process will be recorded in non-GMP master batch records. The oxycodone base will be tested according to agreed upon specifications.

JM will then target the manufacture of estimated amount of [ ] Kg of PF614 under cGMP conditions in the kilo-labs in Devens, MA. The process will be documented in controlled cGMP batch records. All documentation and analytical results will be subject to Quality Control and Quality Assurance review and approval. The final material will be tested against agreed upon specifications and released with a Certificate of Analysis (CoA). The testing is anticipated to be consistent with that shown in the Table below. The material will be packaged and sent accompanied by CoA, SDS, BSE/TSE and Certificate of Compliance documentation.

Proposed batch schedule for PF614:

	Step	No. of Batches	Planned Equipment
Non-GMP	Oxycodone base	[ ]	100-L Glass Jacketed Reactor
	Activated OC (4346.A) (non-isolated)		
	Intermediate G (4346.B) (non-isolated)	[ ]	Up to 100-L Glass Jacketed Reactor
GMP	PF614 TFA salt (4346.C)		
	PF614 crude (4346.D1)	[ ]	Up to 100-L Glass Jacketed Reactor
	PF614 (4346.D)	[ ]	Up to 100-L Glass Jacketed Reactor

Proposed Testing for PF614:

Test Name
Physical Description
Identification: ^{1}H NMR
Identification: FTIR
Identification: HPLC RT
Assay (HPLC, weight %)
Purity/Impurities (HPLC, area %)
Residual Solvents (GC, weight %)
Residual TFA (weight %)
Water Content (Karl Fischer Analysis)

Elemental impurities (As, Cd, Hg, Pb, Co, V, Ni) by ICP
Residue on Ignition

XRPD
Microbial Bioburden USP <61>
Total Aerobic Microbial Count
Total Yeast Mold Count
Absence of Specified Organisms USP <62>
Salmonella
Escherichia coli
Staphylococcus aureus
Pseudomonas aeruginosa
Clostridium
Candida Albicans

Deliverables:

- Target [ ] Kg cGMP of PF614 in one lot.
- CoA, COC, BSE/TSE and SDS.
- Campaign Summary Report.
- Copies of executed batch records.

This estimate is provided solely for budgetary purposes based upon the assumptions stated above and remains subject to revisions (including price and timing).

This stage of the project is expected to be completed [ ] months including release testing from commencement of the work.

Additional Service Offerings

Johnson Matthey has leading capabilities in developing optimal polymorphs, salt forms, crystal morphology and controlled particles through our Pharmorphix® solid form sciences. We offer one of the broadest and most reliable services to ensure effective identification, development and manufacture of your drug candidates and commercial products.

Solid Form Sciences services include:

- Polymorph Screening and Selection of most stable / developable forms
- Salt and/ or Cocrystal screening and selection
- Crystallizing amorphous or difficult-to-crystallize compounds
- Chiral resolution services via crystallization (salt, dynamic kinetic crystallization)
- Crystallisation development
    - Scale up of selected solid form using a range of PAT tools and modelling
    - Critical parameter robustness evaluation
    - Development of optimal isolation processes

Solid form and particle technologies provide drug manufacturers with powerful tools to improve the physicochemical properties of an active pharmaceutical ingredient (API) and address its aqueous solubility.

Particle Technologies services include:

- Crystal engineering
    - Filtration and drying improvement
    - Morphology / particle size modification
- Amorphous Dispersions
    - Screening, evaluation and scale up using Spray Drying / Hot Melt Extrusion
- Particle Size Reduction
    - Dry Milling: Cone milling, Hammer milling, pin milling (10 to 250 microns)
    - Wet Milling: to tighten/control PSD prior to isolation (1 micron to 250 microns)
    - Jet Milling: to produce micronized product (1 micron to 15 microns)
- Preformulation development including physicochemical analysis to better understand and predict in vivo behaviours of an API and completing data packages in preparation for IND application
    - High throughput pKa/LogP determinations
    - Small scale, low throughput dissolution
    - Intrinsic, natural and kinetic Solubility
    - pH profiling

AUTHORIZATION

Proposal Number: 202202-31203

The proposed work may be authorized by returning (via electronic signature, PDF by email, or standard mail services) a signed copy of the proposal to:

Gina DiBartolomeo
Sales & Marketing Specialist
Johnson Matthey
25 Patton Road, Devens, MA 01434

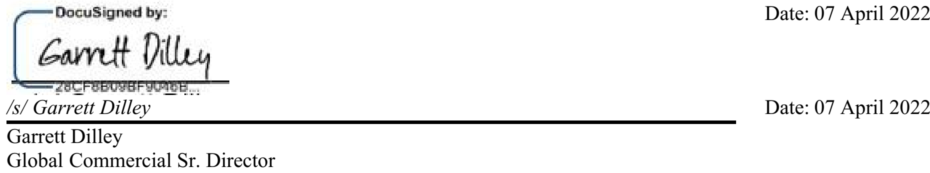
This proposal, including all work and material provided by JM hereunder, shall be governed by the Terms and Conditions. Any other terms or provisions contained in any purchase order or any other form or document provided by Ensysce Biosciences, Inc. are void and of no effect unless otherwise expressly agreed in writing signed by Ensysce Biosciences, Inc. and Johnson Matthey Pharma Services. Except as otherwise expressly agreed by the parties in writing, in the event of any conflict or inconsistency between the terms of this proposal and the Terms and Conditions, the Terms and Conditions shall govern. By its signature below, Ensysce Biosciences, Inc. hereby authorizes JM to perform the work detailed in this proposal subject to the Terms and Conditions.

For: **Ensysce Biosciences, Inc.**

/s/ Lynn Kirkptrick 04/04/2022

Signature
Lynn Kirkpatrick **PO# 22023**
Printed Name

For: **Johnson Matthey Pharmaceutical Materials, Inc.**



Date: 07 April 2022

/s/ Garrett Dilley Date: 07 April 2022

Garrett Dilley
Global Commercial Sr. Director

Exhibit A

Johnson Matthey Pharma Services / Ensysce Biosciences, Inc.

CHANGE ORDER # to PROPOSAL #202202-31203

This Change Order, effective as of , is made to and amends Proposal #202202-31203, dated between Ensysce Biosciences and Johnson Matthey Pharmaceutical Materials, Inc. d/b/a Johnson Matthey Pharma Services ("JM").

The following changes are hereby made to 202202-31203:

I. Change to Fees and Expenses

Additional expense will be billed as: Choose an item.

Proposal contract value due to this Change Order will be increased/decreased by: $

II. Change to Performance Timeline:

The timeline for performance will be Choose an item. by calendar days.

AUTHORIZATION

The proposed work may be authorized by returning (via electronic signature, PDF by email, or standard mail services) a signed copy of the change order to:

Gina DiBartolomeo
Sales & Marketing Specialist
Johnson Matthey 25 Patton Road, Devens, MA 01434

This certifies that the authorized signatories below have reviewed and approved the information and amendments set forth in this Change Order and that Johnson Matthey Pharma Services and Ensysce Biosciences hereby agree to perform their respective obligations under 202202-31203 as revised herein based on the price and time revisions listed above.

	Global Commercial Sr. Director	
Garrett Dilley	Title	Date
Ensysce Biosciences Representative	Title	Date

JM STANDARD TERMS AND CONDITIONS

1 . **Proposal; Governing Provisions** – These terms and conditions shall govern the performance of the services (the "**Services**") to be performed by **Johnson Matthey Pharmaceutical Materials, Inc. doing business as Johnson Matthey Pharma Services** ("**Seller**") under its proposal (the "**Proposal**") to which these terms and conditions are attached, and the client named in such Proposal ("**Buyer**") hereby assents to the Proposal and these terms and conditions herein contained. Any provisions contained in any purchase order or any other form or document provided by Buyer are hereby rejected unless otherwise expressly accepted in writing signed by Buyer and Seller. There are no other representations, agreements, promises or understandings between Buyer and Seller that are not expressed herein or in the Proposal.

2. Changes; Cancellation - If Buyer requests a change in the scope of the Services or requests additional Services, the parties shall negotiate in good faith, and attempt to agree in writing, on a change order setting forth revised terms, revised budget and/or any other revision for such Services. Neither party shall be entitled and/or obligated to implement any part of the changes without prior written agreement between the parties with respect thereto. No cancellation, suspension or deferral of an order by Buyer shall have any force, effect or validity whatsoever except with Seller's written consent, and under conditions which will indemnify and make whole Seller for any costs incurred by Seller due to such changes, cancellation, suspension or deferral or as otherwise set forth in the Proposal.

Notwithstanding anything else to the contrary in these terms and conditions, a party shall be entitled to terminate the Proposal forthwith in writing if the other party shall have a receiver, administrator, administrative receiver or similar officer appointed, or shall pass a resolution for winding-up (other than a winding-up for the purpose of or in connection with any solvent amalgamation or reconstruction) or a court shall make an order to that effect, or if a party shall enter into any composition or arrangement with its creditors (other than relating to a solvent restructuring) or shall cease to carry on business. Termination of the Proposal under this clause will not affect either party's rights accruing before the date of termination.

3. Delivery; Claims; Delays - Unless specified differently in writing, all sales are F.C.A. (Incoterms 2020) Seller's shipping point. Delivery of goods to the carrier at Seller's plant or other loading point shall constitute delivery to Buyer and regardless of shipping terms, all risk of loss or damage in transit shall be borne by Buyer. Seller reserves the right to make delivery in instalments, all such instalments to be separately invoiced and paid for when due per invoice, without regard to subsequent deliveries. Delay in delivery of any instalment shall not relieve Buyer of Buyer's obligations to accept remaining deliveries. Immediately upon Buyer's receipt of any goods shipped hereunder, Buyer shall inspect the same and shall notify Seller in writing of any claims for shortages, defects or damages and shall hold the goods for Seller's written instructions concerning disposition. If Buyer shall fail to so notify Seller within five (5) days after the goods have been received by Buyer, such goods shall conclusively be deemed to conform to the terms and conditions hereof and to have been irrevocably accepted by Buyer.

4. Payment

(a) Payment for the Services shall be in accordance with the milestone or stage payments set out in the Proposal or as otherwise provided in the Proposal. Invoices shall be paid not later than thirty (30) days from the date of issuance (or earlier, to the extent that a payment requires to be made prior to commencement of the Services). Unless otherwise agreed, commencement of product manufacturing Services is subject to receipt of an advance payment of not less than twenty-five percent (25%) of the direct labor budget, together with the estimated purchase price of the raw materials concerned. The advance payment shall be credited proportionately against each invoice payable hereunder in accordance with the percentage of the Services then completed.

(b) If Buyer fails to pay Seller the amounts owed within the time specified in the Proposal, Seller may at its sole discretion choose to: (a) terminate the Proposal on written notice to Buyer; (b) elect to charge and recover from Buyer a further sum of 2% (or such lesser percentage as Seller in its discretion elects) of the unpaid amount of the invoice in question for each month or part month of delay by way of interest; (c) suspend all further work for Buyer pending the payment of such outstanding monies and/or (d) require full payment in advance for any further Services.

5. Taxes and other charges - Any use tax, sales tax, excise tax, duty, custom, inspection or testing fee, or any other tax, fee or charge of any nature whatsoever imposed by any governmental authority on or measured by the transaction between Seller and Buyer, shall be paid by Buyer in addition to the prices quoted or invoiced. In the event Seller is required to pay any such tax, fee, or charge, Buyer shall reimburse Seller therefore; or in lieu of such payment, Buyer shall provide Seller at the time the order is submitted an exemption certificate or other document acceptable to the authority imposing the tax, fee or charge. Materials and waste disposal will be billed at Seller's cost plus 8%.

6. Limited Warranty - Seller warrants that it shall use commercially reasonable efforts to provide the Services pursuant to the Proposal and that its products, if any, shall conform to the description of the products under the Proposal. THIS WARRANTY IS EXCLUSIVE, AND SELLER MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. Seller's warranties made in connection with the products delivered hereunder shall not be effective if Seller has determined, in its sole discretion, that Buyer has misused the products in any manner or has failed to use the products in accordance with instructions, if any, furnished by Seller. Seller's sole and exclusive liability and Buyer's exclusive remedy with respect to products proven to Seller's satisfaction to be defective or nonconforming shall be the repair or replacement of such non-conforming products without charge or refund of the cost to manufacture such products, in Seller's sole discretion, upon the return of such products in accordance with Seller's instructions. IN NO EVENT SHALL SELLER SHALL BE LIABLE FOR ANY LOST PROFITS, REVENUE OR OPPORTUNITY OR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR CONTINGENT DAMAGES. Without limiting the generality of the foregoing, it is acknowledged by Buyer that the Services are in respect of research and development work and as such that Seller cannot guarantee that the Services will be successful and/or that any particular results will be achieved. Buyer agrees that Seller shall have no liability, and Buyer shall not make any claim(s) against Seller, in the event that the Services are unsuccessful and/or do not achieve any particular results. Any claim by Buyer of a breach of the warranty set forth hereinabove must be made in writing to Seller by no later than six (6) months following completion of the Services or thirty (30) days following receipt of the product, as the case may be.

7. Provision of Materials - Where applicable, Buyer shall provide Seller free of charge with such materials (including compounds, substrates and samples) as may be reasonably required by Seller to enable Seller to perform the Services ("**Materials**"). Buyer shall provide Seller with relevant occupational health and safety information in respect of any Materials provided by Buyer, including material safety data sheets. Buyer will provide such toxicity data as is available in respect of the Materials. Buyer warrants that the Materials shall conform with the material safety data sheets and the declared toxicity thereof. Seller shall not use Materials for any other purpose than the conduct of the Services. Materials shall not be analyzed, reverse engineered or used except to the extent necessary to conduct the Services. Buyer warrants that the possession and/or use of the Materials by Seller and/or its Affiliates (as hereinafter defined) in the performance of the work under this Proposal will not infringe any intellectual property rights of a third party and shall indemnify, defend and hold Seller and its Affiliates and their respective directors, officers, employees and affiliates harmless from and against any losses, damages, costs and expenses arising from any third party claim that such use of the Materials, and/or the specific molecule or set of specific molecules, compound, product or material which are the subject matter of the Services provided by Seller, infringes its intellectual property rights.

8. Buyer's Use of Products – Unless otherwise provided in the Proposal, the products and deliverables provided hereunder are intended primarily for laboratory research

purposes in the pharmaceutical area and, unless produced by Seller under cGMP conditions or otherwise agreed in writing, are not to be used for human consumption or any other clinical purposes, including but not limited to *in vitro diagnostic* purposes or for commercial purposes. Buyer acknowledges that the products have not been tested by Seller for safety and efficacy in food, drug, device, cosmetic, commercial or any other use. Buyer warrants that Buyer will properly test, use, manufacture and market any products purchased from Seller and any final articles made from them in accordance with the practices of a reasonable person who is an expert in the field and in strict compliance with all applicable federal and state food, drug, device, and cosmetic and other relevant laws and regulations. Buyer further warrants that any final articles manufactured from Seller's products shall not be adulterated within the meaning of the Federal Food, Drug and Cosmetic Act and shall not be articles which may not, under Sections 404, 505 or 512 of the Act, be introduced into interstate commerce. Buyer has the responsibility to conduct any research necessary to learn the hazards involved in using products purchased from Seller. Seller's products are provided for pharmaceutical research and development purposes and therefore may not be on the Toxic Substances Control Act (TSCA) inventory. In the event Buyer's intended use of the products is subject to TSCA, Buyer hereby assumes all responsibility to assure that the products purchased from Seller are approved for use under TSCA, if applicable, shall notify Seller of such use and shall provide Seller with certification that the product is listed on the TSCA inventory or is exempt from such listing. Buyer also has the duty to warn Buyer's customers and any auxiliary personnel (such as freight handlers, etc.) of any risks involved in using or handling the products. Buyer agrees to comply with instructions, if any, furnished by Seller relating to the use of the products and further agrees not to misuse the products in any manner. If the products purchased from Seller are to be repackaged, relabeled or used as starting materials or components of other products, Buyer will verify Seller's assay of the products. No products purchased from Seller shall be considered to be foods, drugs or cosmetics; nor, except if labeled "For in Vitro Diagnostic Use" to be devices.

9. Ownership and Use of Results

(a) Buyer shall own all right, title and interest in all intellectual property, including without limitation material, data, information, patentable inventions, discoveries and improvements and non-patentable processes and the like created, invented or conceived by Seller specifically and directly resulting from the performance of the Services ("**Results**") and the right to exploit such Results at its sole discretion and risk. Seller assigns to Buyer all such

Results and shall provide reasonable assistance to Buyer in applying for patents with respect to any such Results, the reasonable costs of such assistance being borne by Buyer. Nothing contained in these terms and conditions shall be deemed to grant to Seller any rights or licenses under any patent applications or patents or under any know-how, technology or inventions of Buyer.

(b) Notwithstanding the foregoing, Buyer hereby acknowledges and agrees that, as between Seller and Buyer, Seller shall retain and own all right, title and interest in (i) those properties, methods, processes, procedures, technologies, know-how and other intellectual property owned or controlled by Seller as of the date of the execution of the Proposal and (ii) such additional properties, methods, processes, procedures, technologies, know-how and other intellectual property developed or otherwise acquired by Seller during the course of the performance of the Services but outside of the scope of the work undertaken pursuant to the Proposal and/or such works, information and improvements (and relevant intellectual property rights) related to properties, methods, processes, procedures, technologies, know-how and other intellectual property which relate to Seller's business or operations generally and not specifically to manufacturing Buyer's proprietary compound or technology (collectively, "**Seller Technology**"). Buyer assigns to Seller all such rights, title and interest in and to any Seller Technology and shall provide reasonable assistance to Seller in applying for patents with respect to any such Seller Technology, the reasonable costs of such assistance being borne by Seller. Nothing contained in these terms and conditions shall be deemed to grant to Buyer any rights or licenses under any patent applications or patents or under any know-how, technology or inventions of Seller.

10. Indemnification

(a) Seller shall indemnify, defend and hold harmless Buyer and the officers, directors and employees of Buyer from all losses, liabilities, damages and expenses (including reasonable legal fees and costs) that Buyer may suffer as a result of any claims, suits, demands, actions or other proceedings brought by a third party ("**Claims**") to the extent arising out of (i) the breach by Seller of the provisions of the Proposal or these terms and conditions or (ii) out of the fraud, negligence or willful misconduct of Seller, its employees or agents in the course of Seller's provision of Services pursuant to the Proposal; except, in each case, to the extent such Claim is caused by the fraud, negligence or willful misconduct of Buyer.

(b) Buyer shall indemnify, defend and hold harmless Seller and its Affiliates and their respective officers, directors and employees from all losses, liabilities, damages and expenses (including reasonable legal fees and costs) that Seller and/or its Affiliates may suffer as a result any Claims to the extent arising out of (i) Buyer's breach of the provisions of the Proposal or these terms and conditions or (ii) Buyer's possession, handling or use of any Results, products or other deliverables of the Services provided by Seller after Buyer's receipt thereof; except, in each case, to the extent such Claim is caused by the fraud, negligence or willful misconduct of Seller and/or Affiliates, as the case may be.

(c) In case any action, proceeding or claim shall be brought against one of the parties hereto (an '**Indemnified Party**") in respect of which indemnity may be sought against the other party hereto (the "**Indemnifying Party**") such Indemnified Party shall promptly notify the Indemnifying Party in writing. The failure by an Indemnified Party to notify the Indemnifying Party of such claim shall not relieve the Indemnifying Party of responsibility under this section, except to the extent such failure adversely prejudices the ability of the Indemnifying Party to defend such claim. The Indemnifying Party at its expense, with counsel of its own choice, shall defend against, negotiate, settle or otherwise deal with any such claim, provided that the Indemnifying Party shall not enter into any settlement or compromise of any claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party without the Indemnified Party's prior written consent. The Indemnified Party may participate in the defense of any claim with counsel of its own choice and at its own expense. The parties agree to cooperate fully with each other in connection with the defense, negotiation or settlement of any such claims. In the event that the Indemnifying Party does not undertake the defense, compromise or settlement of any claim, the Indemnified Party shall have the right to control the defense or settlement of such claim with counsel of its choosing.

11. Limit on Liability – The maximum combined aggregate liability of Seller and its Affiliates for any claim or series of related claims howsoever arising, whether in contract (including warranties and/or indemnities), tort (including negligence), breach of statutory duty, misrepresentation, strict liability, local laws or otherwise, shall be limited to an amount equal to the aggregate amount of the fees paid and fees accrued but unpaid to Seller for the relevant Service(s) pursuant to the Proposal as at the date of the occurrence of the event, matter or circumstance giving rise to such claim (or, where there is a series of related claims, the event, matter or circumstance giving rise to the first relevant claim). Seller and its Affiliates shall not be liable for any loss of profit or plant down-time, loss of use, loss of business, loss of margin, loss of contract, loss of goods, loss of goodwill, loss of anticipated savings (in each case whether direct or indirect) or any form of special, indirect or consequential losses arising out of or in connection with the provision of its Services. Nothing in these terms will exclude or limit the liability of Seller and its Affiliates for (i) fraud or fraudulent misrepresentation or (ii) death or personal injury relating to the provision of the Services and arising from the negligence of Seller and/or its Affiliates.

12. Patent Indemnification and Disclaimer - Buyer agrees to indemnify, defend and hold harmless and make whole Seller and its Affiliates from and against any and all liability for any patent, trade secret or other intellectual property infringement, misappropriation or misuse (including attorney's fees and other costs of defending any action)

that Seller and/or its Affiliates may sustain or incur in using any material or information supplied to Seller by Buyer. Seller does not warrant that the use or sale of the Results and/or any products delivered hereunder will not infringe the claims of any United States or foreign patents or any other intellectual property rights that any third-party may have in and to the synthetic process or solid state properties, the product itself or the use thereof in combination with other products or in the operation of any process.

13. Subcontracting – Unless otherwise agreed between Seller and Buyer, Seller may subcontract any or all of its obligations in respect of the Services to be provided to Buyer to any Affiliate of Seller, provided that Seller remains fully responsible to Buyer for any Services performed by its subcontractors as if Seller were providing such Services. Invoices for services may be issued by such subcontractors. For the purposes of these terms and conditions, "**Affiliate**" in relation to a party means any other person that controls, is controlled by or is under common control with such party (where "control" means: (a) to possess, directly or indirectly, the power to direct the management or policies of a person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) to own, directly or indirectly, 50% or more of the voting securities or other ownership interest of such person).

14. Confidentiality – Seller and Buyer each possess valuable information, samples, technical knowledge, specifications, know-how, experience and data of a secret and confidential nature, all of which is regarded by it as a commercial asset of considerable value ("**Confidential Information**"). Each is willing to disclose its Confidential Information on the terms set out in this provision. For the purposes of this provision, the party disclosing its Confidential Information (directly or indirectly) is the "**Discloser**" and the party receiving that information (directly or indirectly) is the "**Recipient**", and "**Disclosed Information**" is Confidential Information disclosed by a party.

(a) The Recipient agrees:

(i) to treat the Discloser's Disclosed Information as secret and strictly confidential and not disclose it to any third party save as provided in this provision; and

(ii) not to use the Discloser's Disclosed Information for any purpose except to the extent required for the provision or receiving (as appropriate) of the Services to which these terms and conditions relate.

(b) The Recipient may disclose the Discloser's Disclosed Information to directors, officers and employees of Recipient or of any of its Affiliates ("**Representatives**") whose knowledge of it is strictly necessary for the provision or receiving (as appropriate) of the Services to which these terms and conditions relate, provided that such Representative is bound by obligations of confidentiality that are at least equivalent to those contained in this provision and the Recipient shall be liable for any disclosure of the Discloser's Disclosed Information by its Representatives in contravention of the obligations to which the Recipient is subject pursuant to this provision as if such disclosure had been made by the Recipient.

(c) The undertakings in paragraphs (a) and (b) shall not apply to Disclosed Information to the extent that:

(i) it is, at the time of disclosure to the Recipient, published or otherwise generally available to the public otherwise than through any act or omission on the part of the Recipient;

(ii) after disclosure by the Discloser, it is published or becomes generally available to the public, otherwise than through any act or omission on the part of the Recipient;

(iii) was in the Recipient's possession at the time of disclosure to it by the Discloser and was not acquired directly or indirectly from the Discloser;

(iv) it was rightfully acquired from others who did not obtain it subject to any obligation of confidentiality to the Discloser; or

(v) it is created or developed by the Recipient wholly independently of the Disclosed Information.

(d) These provisions shall survive termination or expiry.

15. Bribery, Financial Crime and Export Rules

(a) Each party agrees that it will not, in connection with the Services, directly or indirectly, pay, offer, promise to pay or authorise the payment of, any monies or financial or other advantage in violation of any anti-corruption laws and in particular (but without prejudice to the generality of the foregoing) the Bribery Act 2010 and the US Foreign Corrupt Practices Act of 1977. Further, it confirms that it has not taken, nor will take, directly or indirectly, any action in connection with the Services that would cause the other party, or the other party's officers, directors, employees and/or affiliates, to be in violation of any anti-corruption laws including the Bribery Act 2010 and the US Foreign Corrupt Practices Act of 1977.

(b) Each party warrants and represents that it shall comply with all applicable taxation, anti-money laundering and financial crime laws, regulations and rules ("**Financial Crime Laws**") and:

(i) any consideration paid for the purchase of the Services does not constitute the proceeds of crime under any applicable Financial Crime Laws and is not derived from conflict, terrorism or money laundering sources;

(ii) it shall not commit an offence of cheating the public revenue or an offence consisting of being knowingly concerned in, or in taking steps with a view to, the fraudulent evasion of a tax by itself or any other person;

(iii) unless otherwise agreed in writing by Seller, Buyer will only make payments to Seller from an account held in Buyer's name.

(c) Each party acknowledges and agrees that:

(i) the Services (and products incorporating the Services) and confidential information of each party respectively (including technical information constituting technology) may be subject to applicable export control and trade sanction laws, regulations, rules and authorisations or licences, including Council Regulation (EC) No. 428/2009, the UK Export Control Act 2002, the US Export Administration Regulations, the US International Traffic in Arms Regulations, and any local regulations to which Buyer and Seller may be subject or any legislation replacing the foregoing and any orders issued under the foregoing (the "**Export Control Rules**");

(ii) each party shall be responsible for its compliance with the Export Control Rules and shall not do anything which would cause the other party to be in breach of the Export Control Rules. Neither party will, nor will procure that any person acting on its behalf will, use, sell, re-sell, export, re-export, transfer, divert, distribute, dispose of, disclose or otherwise deal with the Services (or products incorporating the Services) and/or confidential information of the other party, directly or indirectly, to any country, destination or person without first obtaining any required export licence or other governmental authorisation and completing such formalities as may be required by the Export Control Rules.

(d) Each party agrees to indemnify the other party against any losses, liabilities, damages, costs (including reasonable legal fees) and expenses incurred as a result of the such party's breach of the provisions of Sections 15(a), (b) or (c) above by it or its employees, agents, contractors or representatives. This Section 15 shall survive termination, completion or expiry of the Proposal.

16. Data Protection

(a) For the purposes of this Section 16:

(i) Data Protection Laws means all data protection laws, regulatory requirements, guidance and codes of practice, including Regulation (EU) 2016/679 (the so-called "GDPR"), the Privacy and Electronic Communications (EC Directive) Regulations 2003 (the so-called "PECR") and the Data Protection Act 2018;

(ii) "Controller", "Processor", "Personal Data", "Process", "Processing", "Processed" and "Data Subject" have the meanings given to those terms by the Data Protection Laws.

(b) With regard to any Personal Data processed by Seller or Buyer in connection with the Services, the parties will respectively each be a Controller in respect of such processing.

(c) Seller and Buyer shall each comply with the requirements of the Data Protection Laws applicable to Controllers in connection with the Services and shall not knowingly do anything or permit anything to be done which might lead to a breach by the other of the Data Protection Laws.

17. Returns - Products may not be returned for credit except with Seller's permission, and then only in strict compliance with Seller's return-shipment instructions.

18. Force Majeure

(a) Either party shall be excused from performing any of its obligations with respect to the Services if their performance is delayed or prevented by any cause beyond such party's control, including, but not limited to, war, explosion, hostilities, revolution, civil commotion, act of terrorism, strike, lockouts or other industrial disputes, lack of or failure of utility services or transportation facilities or materials, epidemic, pandemic, rain, fire, wind, earthquake, flood or because of any law, order, proclamation, regulation, sanction, embargo, or ordinance of any government, or of any subdivision thereof, or because of Acts of God, ("**Force Majeure**"). Performance shall be excused only to the extent of and during the reasonable continuance of such Force Majeure and/or the consequences thereof. Any agreed deadline or time for performance of the Services or part thereof which falls due during or subsequent to the occurrence of any Force Majeure herein shall be automatically extended for a period of time equal to the period of such Force Majeure.

(b) Each party shall promptly notify the other party in writing upon becoming aware of an event of Force Majeure as well as the expiration thereof. However, if the Force Majeure persists for a period of one (1) month after receipt of notice, such other party shall be entitled to terminate the Proposal and the Services in writing without further notice.

19. General

(a) No waiver by Seller of any breach of the Proposal by Buyer shall be considered as a waiver of any subsequent breach of the same or any other provision.

(b) If any provision of these terms and conditions is held by any competent authority to be invalid or unenforceable in whole or in part the validity of the other provisions of these terms and conditions and the remainder of the provision in question shall not be affected.

(c) No party shall assign the Proposal without the prior written consent of the other party, which consent shall not be unreasonably withheld or delayed, provided however that a party may assign or subcontract any or all of its rights and obligations under Proposal to an Affiliate.

20. Governing Law – Any contract resulting from acceptance of these terms and conditions, and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims), shall be construed in accordance with and governed by the laws of the Commonwealth of Massachusetts, USA, without reference to its conflicts of laws rules, and the parties submit to the non-exclusive jurisdiction of the federal and state courts of the Commonwealth of Massachusetts, USA.

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in this Amendment No. 1 to the Registration Statement on Form S-1 and related Prospectus of our report dated March 31, 2022, except with respect to the impact of the reverse stock split discussed in Notes 2 and 12, as to which the date is November 16, 2022 (which report includes an explanatory paragraph regarding the existence of substantial doubt about the ability of Ensysce Biosciences, Inc. (the “Company”) to continue as a going concern), relating to the consolidated financial statements of the Company as of December 31, 2021 and 2020 and for each of the two years in the period ended December 31, 2021, and to the reference to us under the heading “Experts” included in the Prospectus, which is part of this Registration Statement.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
November 16, 2022