UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38306

Ensysce Biosciences, Inc.
(Exact Name of Registrant as Specified in its Charter)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	ENSC	The Nasdaq Stock Market LLC

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 13(a) of the Exchange Act. ☐

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of May 10, 2023, the registrant had 1,284,583 shares of common stock, $0.0001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "will" and "would," or the negative of these terms or other similar expressions intended to identify statements about the future. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include, without limitation, statements about:

- our estimates regarding expenses, revenue, capital requirements and timing and availability of and the need for additional financing will almost certainly not match actual amounts and timing;
- our ability to continue as a going concern for the next twelve months;
- 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;
- the need for substantial additional funding to complete the development and commercialization of our product candidates;
- 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 Quarterly Report on Form 10-Q;
- 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 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 establish and 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;
- other factors disclosed in this Quarterly Report on Form 10-Q; and
- other factors beyond our control.

The forward-looking statements contained in this Quarterly Report on Form 10-Q are based on Ensysce's current expectations and beliefs concerning future developments and their potential effects on Ensysce. There can be no assurance that future developments affecting Ensysce will be those that Ensysce has anticipated. These forward-looking statements involve risks, uncertainties (some of which are beyond Ensysce's control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022 and other filings with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should any of the assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Moreover, the occurrence of the events described in the "Risk Factors" in our Annual Report on Form 10-K may adversely affect Ensysce. Ensysce will not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

GLOSSARY

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
2023 Offering	The Company's February 2023 registered direct offering of common stock and private placement warrants for aggregate consideration of $3.0 million
ADFs	Abuse deterrent formulations
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
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
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
GEM Global	GEM Global Yield LLC SCS
GEM Warrants	4,608 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 $8.58 per share
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 29,303 shares of our common stock at a weighted average exercise price of $2,734.41 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
Prior Warrants	Warrants issued pursuant to the Securities Purchase Agreement. The Prior Warrants issued in (i) 2021 are exercisable for an aggregate of 4,512 shares of our common stock at an exercise price of $187.20 per share and (ii) 2022 are exercisable for an aggregate of 38,894 shares of our common stock at an exercise price of $24.07 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 41,666 shares of our common stock at an exercise price of $2,760.00 per share
R&D	Research and Development
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

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

ENSYSCE BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 1,415,765	$ 3,147,702
Unbilled receivable	289,312	276,821
Right-of-use asset	19,015	27,165
Prepaid expenses and other current assets	1,646,553	1,847,481
Total current assets	3,370,645	5,299,169
Other assets	544,217	585,883
Total assets	$ 3,914,862	$ 5,885,052
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,598,166	$ 2,943,791
Accrued expenses and other liabilities	2,358,682	2,226,494
Lease liability	19,120	27,315
Notes payable and accrued interest ($0 and $4,063,431 at fair value at March 31, 2023 and December 31, 2022, respectively)	-	4,266,610
Total current liabilities	3,975,968	9,464,210
Long-term liabilities:		
Notes payable, net of current portion (at fair value)	-	140,148
Liability classified warrants	91,318	310,346
Total long-term liabilities	91,318	450,494
Total liabilities	$ 4,067,286	$ 9,914,704
Commitments and contingencies (Note 6)		
Stockholders' deficit		
Preferred stock, $0.0001 par value, 1,500,000 shares authorized, no shares issued and outstanding at March 31, 2023 (unaudited) and December 31, 2022	-	-
Common stock, $0.0001 par value, 250,000,000 shares authorized at March 31, 2023 (unaudited) and December 31, 2022; 1,284,664 and 534,571 shares issued at March 31, 2023 (unaudited) and December 31, 2022, respectively; 1,284,583 and 534,490 shares outstanding at March 31, 2023 (unaudited) and December 31, 2022, respectively	128	53
Additional paid-in capital	113,293,834	107,216,566
Accumulated deficit	(113,127,237)	(110,931,063)
Total Ensysce Biosciences, Inc. stockholders' equity (deficit)	166,725	(3,714,444)
Noncontrolling interests in stockholders' deficit	(319,149)	(315,208)
Total stockholders' deficit	(152,424)	(4,029,652)
Total liabilities and stockholders' deficit	$ 3,914,862	$ 5,885,052

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

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

	Three Months Ended March 31,	
	2023	**2022**
Federal grants	$ 789,635	$ 603,098
Operating expenses:		
Research and development	1,796,015	3,140,096
General and administrative	1,554,855	2,265,806
Total operating expenses	3,350,870	5,405,902
Loss from operations	(2,561,235)	(4,802,804)
Other income (expense):		
Change in fair value of convertible notes	146,479	2,767,178
Change in fair value of liability classified warrants	219,028	2,794,398
Loss on debt conversions	-	(1,702,642)
Interest expense, net	(1,497)	(15,021)
Other income and expense, net	5,419	7,966
Total other income, net	369,429	3,851,879
Net loss	$ (2,191,806)	$ (950,925)
Net loss attributable to noncontrolling interests	(3,941)	182
Deemed dividend related to warrants down round provision	8,309	715,579
Net loss attributable to common stockholders	$ (2,196,174)	$ (1,666,686)
Net loss per basic and diluted share:		
Net loss per share attributable to common stockholders, basic and diluted	$ (2.08)	$ (14.66)
Weighted average common shares outstanding, basic and diluted	1,054,202	113,696

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, 2021	102,678	**$ 10**	**$ 77,967,314**	**$ (85,845,567)**	**$ (279,815)**	**$ (8,158,058)**
Consultant compensation	208	0	54,250	-	-	54,250
Conversion of convertible notes	19,618	2	8,075,341	-	-	8,075,343
Settlement of restricted stock units	2,280	0	(0)	-	-	-
Stock-based compensation	-	-	2,090,663	-	-	2,090,663
Deemed dividend related to warrants down round provision	-	-	715,579	(715,579)	-	-
Net loss	-	-	-	(951,107)	182	(950,925)
Balance on March 31, 2022	124,784	**$ 12**	**$ 88,903,147**	**$ (87,512,253)**	**$ (279,633)**	**$ 1,111,273**
Balance on December 31, 2022	**534,490**	**$ 53**	**$ 107,216,566**	**$ (110,931,063)**	**$ (315,208)**	**$ (4,029,652)**
Settlement of restricted stock units	312	-	-	-	-	-
Conversion of convertible notes	408,582	41	3,056,851	-	-	3,056,892
Settlement of commitment fee	44,444	4	399,996	-	-	400,000
Public offering, net	297,619	30	2,689,022			2,689,052
Transaction costs associated with public offering	-	-	(194,043)	-	-	(194,043)
Stock-based compensation	-	-	117,133	-	-	117,133
Reverse split fractional shares	(864)	-	-	-	-	-
Deemed dividend related to warrants down round provision	-	-	8,309	(8,309)	-	-
Net loss	-	-	-	(2,187,865)	(3,941)	(2,191,806)
Balance on March 31, 2023	**1,284,583**	**$ 128**	**$ 113,293,834**	**$ (113,127,237)**	**$ (319,149)**	**$ (152,424)**

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

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

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (2,191,806)	$ (950,925)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of asset	-	(4,500)
Accrued interest	1,497	15,021
Change in fair value of convertible notes	(146,479)	(2,767,178)
Change in fair value of liability classified warrants	(219,028)	(2,794,398)
Loss on debt conversions	-	1,702,642
Stock-based compensation	117,133	402,434
Lease cost	(46)	(46)
Changes in operating assets and liabilities:		
Unbilled receivable	(12,491)	(366,880)
Prepaid expenses and other assets	242,594	581,840
Accounts payable	(1,345,624)	658,526
Accrued expenses and other liabilities	(52,669)	86,450
Net cash used in operating activities	(3,606,919)	(3,437,014)
Cash flows from investing activities:		
Proceeds from sale of assets	-	4,500
Net cash provided by investing activities	-	4,500
Cash flows from financing activities:		
Proceeds public offering, net	2,689,052	-
Transaction costs associated with public offering	(194,043)	-
Repayment of convertible notes	(415,351)	-
Repayment of financed insurance premiums	(204,676)	(391,270)
Net cash provided by (used in) financing activities	1,874,982	(391,270)
Decrease in cash and cash equivalents	(1,731,937)	(3,823,784)
Cash and cash equivalents beginning of period	3,147,702	12,264,736
Cash and cash equivalents end of period	$ 1,415,765	$ 8,440,952
Supplemental cash flow information:		
Income tax payments	$ -	$ -
Supplemental disclosure of non-cash investing and financing activities:		
Stock-based compensation	$ -	$ 1,742,479
Conversions of convertible notes into common stock	$ 3,056,892	$ 6,372,701
Cash true-up liability	$ 584,857	$ -
Settlement of commitment fee in shares	$ 400,000	$ -
Deemed dividend related to warrants down round provision	$ 8,309	$ 715,579

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 79.2%-owned subsidiary, EBIR, Inc. ("EBIR", formerly known as 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 proprietary technology platforms to develop safer prescription drugs. 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.

In 2020, the Company commenced an initiative to develop a therapeutic for the treatment of certain coronavirus infections through the formation of a separate entity, EBIR, a Delaware corporation. Pursuant to the certificate of incorporation, EBIR 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 EBIR, with 19.8% and 1.0% of the shares held by certain key personnel of the Company and an unrelated party, respectively. The non-Ensysce owned shares and the activity are reflected on the financial statements as Noncontrolling interests.

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 months ended March 31, 2023, are not necessarily indicative of the results that may be expected for the year ending December 31, 2023. 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, 2022, which may be found in the Company's Form 10-K filed with the SEC on March 30, 2023.

Reverse stock split

In March 2023, the Company completed a 1-for-12 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. The number of authorized shares and the par value of the shares did not change as a result of the reverse stock split.

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 $113.1 million at March 31, 2023. 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 4,608 warrants with a five-year term to purchase common stock of Ensysce at an exercise price of $2,402.40 per share (Note 8). The Company was 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 was paid in January 2023 in common stock of the Company. Usage of the GEM facility is limited by other agreements of the Company. The Company has not raised any capital to date pursuant to the GEM facility and may not raise any capital pursuant to it prior to its expiration.

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 accrued research and development services, the valuation allowance of deferred tax assets resulting from net operating losses, and the fair value of 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 currently exceed federally insured limits. 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. Property and equipment are fully depreciated as such there is no depreciation recognized in the periods presented. Depreciation expense is classified in general and administrative expense in the accompanying consolidated statements of operations.

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 March 31, 2023 and December 31, 2022, 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 and 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 simulation, 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 simulation. 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 and 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 simulation, 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 simulation. 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 liabilities measured and recorded at fair value on the Company's consolidated balance sheets as of March 31, 2023 and December 31, 2022.

	March 31, 2023			
	Total	**Level 1**	**Level 2**	**Level 3**
Liability classified warrants	$ 91,318	$ -	$ -	$ 91,318
Total	$ 91,318	$ -	$ -	$ 91,318

	December 31, 2022			
	Total	**Level 1**	**Level 2**	**Level 3**
Fair value of convertible note	$ 4,203,579	$ -	$ -	$ 4,203,579
Liability classified warrants	310,346	-	-	310,346
Total	$ 4,513,925	$ -	$ -	$ 4,513,925

The following table summarizes the change in fair value of the Company's Level 3 assets and liabilities for the quarter ended March 31, 2023:

	Total	**Convertible note**	**Liability classified warrants**
Fair value, December 31, 2022	$ 4,513,925	$ 4,203,579	$ 310,346
Conversions	(3,056,892)	(3,056,892)	-
Cash payments	(415,351)	(415,351)	-
Cash true-up liability	(584,857)	(584,857)	-
Change in fair value	(365,507)	(146,479)	(219,028)
Fair value, March 31, 2023	$ 91,318	$ -	$ 91,318

Federal Grants

In September 2018, the National Institutes of Health ("NIH") through the National Institute on Drug Abuse ("NIDA") 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 $10.7 million.

In September 2019, the NIH/NIDA 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 was approximately $5.4 million.

The Company recognizes revenue when costs related to the grants are incurred and assessed as reimbursable. 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 March 31,	
	2023	**2022**
MPAR	$ 481,279	$ 504,470
TAAP/OUD	308,356	98,628
Total	$ 789,635	$ 603,098

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 three months ended March 31, 2023, 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.

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 March 31,	
	2023	**2022**
Stock options	26,354	24,111
RSUs	691	1,788
Warrants	858,609	87,878
Convertible notes	-	5,437
Total	885,654	119,214

Recently Issued Accounting Pronouncements

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 adopted the standard with an effective date of January 1, 2023 and the adoption did not have a significant impact on the consolidated financial statements.

NOTE 4 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

	March 31, 2023	December 31, 2022
Prepaid research and development	$ 1,180,547	$ 1,300,473
Prepaid insurance	314,990	445,583
Other prepaid expenses	151,016	101,425
Total prepaid expenses and other current assets	$ 1,646,553	$ 1,847,481

NOTE 5 – ACCRUED EXPENSES AND OTHER LIABILITIES

	March 31, 2023	December 31, 2022
Accrued research and development	$ 1,293,348	$ 1,332,713
Share subscription facility commitment fees	-	400,000
Professional fees	393,077	421,530
Other accrued liabilities	672,257	72,251
Total accrued expenses and other liabilities	$ 2,358,682	$ 2,226,494

NOTE 6 – COMMITMENTS AND CONTINGENCIES

Purchase Commitments

As of March 31, 2023, the Company's commitments included an estimated $20.4 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 March 31, 2023 and December 31, 2022, 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

The Company's current lease agreement (as amended) has a term that extends through October 31, 2023 with no option to renew. As of March 31, 2023, the future lease payments totaled $19,120. The Company recognized total rent expense of $8,375 in the three months ended March 31, 2023 and $7,834 in the three months ended March 31, 2022.

NOTE 7 – NOTES PAYABLE

The Company's outstanding debt balance was zero as of March 31, 2023.

The following table provides a summary of the Company's outstanding debt as of December 31, 2022:

	Principal balance	Accrued interest	Fair value adjustment	Net debt balance
2022 Notes	$ 3,905,264	$ 10,544	$ 287,771	$ 4,203,579
Financed insurance	195,273	7,906	-	203,179
Total	$ 4,100,537	$ 18,450	$ 287,771	$ 4,406,758

The interest expense recognized for financed insurance was as follows:

	Three months ended March 31,	
	2023	2022
Stated interest accrual	$ 1,497	$ 2,004
Total	$ 1,497	$ 2,004

2021 Notes

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 notes included interest at a rate of 5% per annum, in addition to an original issue discount of 6%. The interest could be settled in cash or shares at the option of the Company and was payable together with monthly redemptions of the outstanding principal amount of the debt.

The Company elected to apply the fair value option to the measurement of the 2021 Notes. The total initial fair value of the debt at issuance was $15.9 million. The Company recorded total issuance costs of $1.9 million representing investment banking and legal fees of $1.0 million and original issue discounts of $0.9 million. The 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.

The 2021 Notes were settled on October 11, 2022 and were not outstanding during the quarter ending March 31, 2023.

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 $12.09 million which included a loss upon issuance of $3.6 million 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 and $0.6 million of legal and investment banking fees, which were immediately expensed.

In connection with each of the first and second closings of the 2022 Notes the Company also issued warrants to purchase 38,894 shares of the Company's common stock. The warrants had an original exercise price of $170.04 and are exercisable for five 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 $187.20.

The proceeds of the 2022 Notes were 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 Company triggered this provision in connection with the public offering of securities in December of 2022, the resulting principal payments and interest were reflected as a reduction to the outstanding balance of the 2022 Notes. The 8% premium was paid in cash and was reflected as interest expense within the consolidated statement of operations.

The 2022 Notes were scheduled to 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 outstanding principal and interest balances were satisfied in March 2023.

The following table provides a summary of the Company's 2022 Notes conversions during the quarter ended March 31, 2023:

	Shares	Weighted Average Conversion Price	Conversion Value
During the quarter ended March 31, 2023	408,582	$ 7.48	$ 3,056,892

In January 2023, the Company entered into a letter agreement to reduce the conversion price for the remaining balance of the Company's outstanding 2022 Notes from $24.07 to $9.01 for the period from January 12, 2023 until May 12, 2023. Cash true-up payments totaling $0.6 million for conversions below the adjusted price are due to be paid within 120 days from January 12, 2023 in accordance with the Letter Agreement. Such payments due are recorded as Accrued Expenses and Other Liabilities (Note 5).

Financed insurance premiums

During the year ended December 31, 2022, the Company financed its directors' and officers' liability insurance in the amount of $399,949, the liability was paid in full by March 31, 2023. The Company paid a total of $9,402 in interest from inception through March 2023 when the note will be paid in full. The Company expensed $1,497 of interest for the three months ended March 31, 2023.

NOTE 8 - STOCKHOLDERS' EQUITY

In June 2021, 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 March 31, 2023 and December 31, 2022, there were no shares of preferred stock issued and outstanding.

Preferred Stock

On January 31, 2023, the Board of Directors declared a dividend of 0.001 of a share of Series A Preferred Stock, par value $0.0001 per share, for each outstanding share of the Company's common stock to stockholders of record on February 13, 2023. Each full share of the Series A Preferred Stock entitled holders to 1,000,000 votes per share with respect to the reverse stock split proposal and the adjournment proposal at the Company's special meeting of stockholders on March 23, 2023. The Series A Preferred Stock had no dividend rights and was fully redeemed following the effectiveness of a reverse stock split on March 31, 2023.

Warrants

On March 31, 2023, outstanding warrants to purchase shares of common stock are as follows:

Reference	Shares Underlying Outstanding Warrants	Exercise Price	Description	Classification
(a)	70,969	$ 2,400.00 - 2,760.00	LACQ warrants	Equity
(b)	4,608	$ 8.58	Share subscription facility	Equity
(c)	4,512	$ 187.20	2021 Notes	Liability
(d)	38,894	$ 24.07	2022 Notes	Liability
(e)	549,987	$ 16.80	Public offering	Equity
(f)	318,451	$ 8.84	Public offering	Equity
	987,421			

a) On June 30, 2021, as a result of the Closing, the Company assumed a total of 78,751 warrants previously issued by LACQ (subsequently in December 2022, 7,782 warrants were cancelled). The warrants provide holders the right to purchase common stock at a strike price of between $2,400.00 and $2,760.00 per share and expire June 30, 2026, five years following the completion of the Business Combination. A total of 41,666 of the outstanding warrants are public warrants which trade on the OTC Pink Open Market under the ticker symbol ENSCW. The remaining 29,303 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 2,083 warrants issued on June 30, 2021 from $2,760.00 to $2,400.00.

b) On July 2, 2021, upon public listing of the Company's shares, the Company issued 4,608 warrants to purchase common stock pursuant to the share subscription facility. The warrants have a three-year life. The grant date fair value of the warrants, based on the $3,477.60 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.

The warrants have been subject to multiple exercise price reductions 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 (primarily the result of the conversions of the 2021 Notes and the 2022 Notes). The adjustments have progressed from the original exercise price of $2,402.40 per share to the current exercise price at March 31, 2023 of $8.58 per share. 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 and November 5, 2021, the Company issued 1,504 and 3,008 warrants in connection with the issuance of the 2021 Notes. The warrants were immediately exercisable with an exercise price of $1,831.20 (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 2022, the exercise price of these warrants was adjusted down to $187.20.

d) On July 1, 2022 and August 9, 2022, the Company issued 19,447 warrants each in connection with the issuance of the 2022 Notes. The warrants were immediately exercisable with an exercise price of $170.04 (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 and August 8, 2027, respectively. As a result of the issuance of shares and warrants in connection with the December public offering, the exercise price of these warrants was adjusted down to $24.07.

e) On December 9, 2022, the Company issued 549,987 equity classified warrants in connection with a public offering. The warrants were immediately exercisable with an exercise price of $16.80 (subject to downward revision protection in the event the Company makes certain issuance of common stock at prices below the exercise price) and expire on December 9, 2027.

f) On February 6, 2023, the Company issued 318,451 equity classified warrants in connection with a public offering. The warrants were immediately exercisable with an exercise price of $8.58 - $12.60 (subject to downward revision protection in the event the Company makes certain issuance of common stock at prices below the exercise price) and expire on February 2, 2028, and August 7, 2028.

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:

	Stock price	Exercise price	Expected term (years)	Volatility	Risk free rate
(a) LACQ warrants (grant date varies)	$ 3,477.60	$ 2,400.00 - 2,760.00	3.00	110.0%	0.5%
(b) Share subscription facility (grant date 7/2/21)	$ 3,477.60	$ 2,402.40	3.00	110.0%	0.5%
(b) Share subscription facility (remeasurement date varies)	$ 7.01- 1,029.60	$ 8.58-1,080.00	1.41 - 2.49	92.6% - 125.3%	1.0% - 4.9%
(c) Liability classified warrants (grant date 9/24/21)	$ 1,077.60	$ 1,831.20	5.00	94.1%	1.0%
(c) Liability classified warrants (grant date 11/5/21)	$ 540.00	$ 1,831.20	5.00	94.1%	1.0%
(c) Liability classified warrants (remeasured at 3/31/23)	$ 4.86	$ 187.20	3.50-3.60	102.9% - 103.4%	3.8%
(d) Liability classified warrants (grant date 7/1/22)	$ 136.80	$ 170.04	5.00	98.9%	2.9%
(d) Liability classified warrants (grant date 8/9/22)	$ 127.20	$ 170.04	5.00	102.8%	3.0%
(d) Liability classified warrants (remeasured at 3/31/23)	$ 4.86	$ 24.07	4.25-4.36	101.2% - 102.1%	3.6%

NOTE 9 - STOCK-BASED COMPENSATION

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 18,432 options outstanding under Former Ensysce stock plans and reserves for issuance an additional 4,166 shares for future awards under the 2021 Omnibus Plan. No further awards may be made under the Former Ensysce stock plans.

In January 2022, the 2021 Omnibus Plan was amended and restated to include an additional 12,500 shares available for future grant and to provide for future annual increases. In February 2023, the Company’s Board approved an annual increase of 26,725 shares available for future grant.

The Company recognized within general and administrative expense stock-based compensation expense of $96,270 and $373,944 for the three months ended March 31, 2023 and 2022, respectively. During the three months ended March 31, 2023 and 2022, the Company recognized stock-based compensation expense of $20,863 and $28,490, respectively, within research and development expense.

Option Activity

There were no stock options granted during the three months ended March 31, 2023. During the three months ended March 31, 2022, the Company granted stock options to purchase an aggregate of 8,275 shares of common stock to employees, consultants and members of the Board. The options vest over periods between zero and four years and have an exercise price of between $259.20 and $1,507.20 per share.

The following table summarizes the Company's stock option activity during the three months ended March 31, 2023:

	Options	Weighted average Exercise price	Weighted average Remaining contractual life	Intrinsic value
Outstanding at December 31, 2022	26,334	$ 707.63	6.53	$ -
Granted	-	-	-	-
Exercised	-	-	-	-
Expired / Forfeited	-	-	-	-
Outstanding at March 31, 2023	26,334	$ 707.63	6.29	-
Exercisable at March 31, 2023	23,922	729.16	-	-
Vested and expected to vest	26,334	$ 707.63	6.29	-

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 2023):

	Three Months Ended March 31, 2022
Exercise price	$ 259.20 - 1,507.20
Expected stock price volatility	76.12% - 95.87%
Expected term (years)	5.19 - 10.00
Risk-free interest rate	1.52% -2.20%
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 three months ended March 30, 2022 was $1.01.

As of March 31, 2023, the Company had an aggregate of $296,845 of unrecognized share-based compensation cost, which is expected to be recognized over the weighted average period of 1.48 years.

Restricted Stock Units

The following table summarizes the Company's restricted stock units activity during the three months ended March 31, 2023:

	Restricted Stock Units	Weighted average fair value
Outstanding at December 31, 2022	1,003	$ 120.02
Released	(312)	101.40
Outstanding at March 31, 2023	691	$ 128.43

There were no restricted stock units granted or forfeited during the three months ended March 31, 2023. 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:

	March 31, 2023
Awards outstanding under the 2021 Omnibus Incentive Plan	27,025
Awards available for future grant under 2021 Omnibus Incentive Plan	31,294
Warrants outstanding	987,421
Total shares of common stock reserved for future issuance	1,045,740

NOTE 10 - RELATED PARTIES

On December 9, 2022, the Company completed a public offering for the sale of 241,666 shares of common stock at $16.80 per share and issued 550,000 warrants with an exercise price of $16.80 per share that expire five years following the date of issuance. A Board member purchased 29,761 shares of common stock and was issued 59,523 warrants exercisable for common stock in the public offering.

In July 2022, the Chief Executive Officer and a Board member transferred 3,838 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, 3,838 shares of unregistered and restricted common stock were subsequently issued by the Company to the related parties as reimbursement and recognized under the consolidated statement of changes in stockholders' deficit.

NOTE 11 – SUBSEQUENT EVENTS

On May 12, 2023, the Company completed a public offering of an aggregate of 1,800,876 shares of its common stock (or pre-funded warrants in lieu thereof), Series A-1 warrants to purchase up to 1,800,876 shares of common stock and Series A-2 warrants to purchase 1,800,876 shares of common stock, at a combined public offering price of $3.887 per share (or pre-funded warrant in lieu thereof) and accompanying warrants. The Series A-1 warrants have an exercise price of $3.637 per share and expire five years from the date of issuance, and the Series A-2 warrants have an exercise price of $3.637 per share and expire eighteen months from the date of issuance. The Company received gross proceeds of approximately $7.0 million before the deduction of placement agent fees and offering expenses.

On May 12, 2023, the Company paid $0.6 million of cash true-up payments to holders of the 2022 Notes (Note 7).

Item 2. 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 report. 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 within Part II-Other Information - titled "Item 1A. Risk Factors."

References in the following discussion to "we", "us", "our" and the "Company" refer to Ensysce Biosciences, Inc. and its consolidated subsidiaries following the Closing of the Business Combination. Unless the context otherwise requires, references to "LACQ" refer to Leisure Acquisition Corp., a Delaware corporation, prior to the Closing.

Overview

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

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

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

We have incurred significant operating losses since inception and we expect to continue to incur net losses for the foreseeable future. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing development activities, particularly if and as we:

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

We have incurred and expect to continue to incur costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other expenses. We may never become profitable.

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

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

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

We have generated limited revenues, have incurred significant operating losses since our inception and expect to continue to incur operating losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern. Our future viability is dependent on our ability to raise additional capital to finance our operations.

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

Convertible Promissory Notes

On September 24, 2021, we entered into the SPA for an aggregate financing of $15.0 million with institutional investors. A first closing under the SPA occurred on September 24, 2021 and a second closing under the SPA occurred on November 5, 2021. At the first closing, the Company issued to the investors (i) senior secured convertible promissory notes in the aggregate principal amount of $5.3 million for an aggregate purchase price of $5.0 million (collectively, the "*First Closing Notes*") and (ii) warrants to purchase 18,058 shares of the Company's common stock in the aggregate at an exercise price of $152.60 per share. At the second closing, the Company issued to the institutional investors referenced above, (i) senior secured convertible promissory notes in the aggregate principal amount of $10.6 million (collectively, the "*Second Closing Notes*", together with the First Closing Notes, the "*2021 Notes*") for an aggregate purchase price of $10.0 million and (ii) warrants to purchase 36,116 shares of the Company's common stock in the aggregate at an exercise price of $152.60 per share. The 2021 Notes were satisfied on October 10, 2022.

On June 30, 2022, we entered into an $8.0 million convertible financing agreement with institutional investors (the "2022 Notes"). 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. The remaining amount of principal and interest on the 2022 Notes was repaid in the first quarter of 2023. However, we remain obligated under the 2022 Notes to pay additional cash as true-up payments for interest or redemption amounts that we paid in shares of common stock that were valued below $24.07 or the lower conversion price of $9.01 in effect between January 12, 2023 and May 12, 2023. The true-up payments compensate for the difference between the value of a share and the conversion price in effect at the time of redemption, multiplied by the number of shares paid. The true-up payments are due (in cash) on May 12, 2023.

In connection with each of the first and second closings of the 2022 Notes we also issued warrants to purchase 38,894 shares of the Company's common stock. The warrants have an exercise price of $24.07and are exercisable for five years following issuance of the 2022 Notes. The issuance of these warrants required us to reduce the conversion price of the 2021 Notes and the exercise price of the outstanding warrants associated with the 2021 Notes to $187.20.

The proceeds of the 2022 Notes are being used for working capital purposes subject to certain customary restrictions are secured by the Company's rights to its patents and licenses. We are 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, we carry out one or more capital raises in excess of $5.0 million, the holder has the right to require us 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). In connection with a financing which occurred in December 2022, we repaid $0.7 million of principal on the 2022 Notes and paid an additional $0.1 million of interest and premium payments.

2022 Underwriting Agreement

On December 7, 2022, we entered into an underwriting agreement (the "*Underwriting Agreement*") with Lake Street Capital Management, LLC (the "*Underwriter*"), pursuant to which we agreed to issue and sell (i) 190,000 shares (the "*Firm Shares*") of the Company's common stock, par value $0.0001 per share (the "*Common Stock*"), (ii) pre-funded warrants (the "*Pre-Funded Warrants*") to purchase 51,666 shares of Common Stock and (iii) warrants to purchase 483,333 shares of Common Stock (the "*Common Warrants*" and, collectively with the Pre-Funded Warrants, the "*Warrants*") to the Underwriter in a public offering (the "*Offering*"). In addition, under the terms of the Underwriting Agreement, the Company granted the Underwriter the option, for 45 days from the closing of the Offering, to purchase up to 28,500 additional shares of Common Stock and Common Warrants to purchase up to an additional 72,500 shares of Common Stock (the "*Option Shares*" and, together with the Firm Shares, the "*Shares*").

In lieu of a purchase of Common Stock that would otherwise result in an investor's beneficial ownership exceeding 4.99% (or, at the election of the investor, 9.99%) of the outstanding Common Stock, a Pre-Funded Warrant was offered, each of which enables the investor to purchase one share of Common Stock at an exercise price of $0.0001. Each Pre-Funded Warrant will be exercisable upon issuance and will expire when exercised in full (all Pre-Funded Warrants were exercised immediately upon issuance). Each Pre-Funded Warrant is being sold with a Common Warrant to purchase two shares of Common Stock. The public purchase price of one share of Common Stock and accompanying Common Warrant to purchase two shares of Common Stock is $16.80 and the combined purchase price of one Pre-Funded Warrant and accompanying Common Warrant to purchase two shares of Common Stock is $16.80. The Underwriter agreed to purchase the Firm Shares from the Company pursuant to the Underwriting Agreement at a price of $15.62 per share.

Each Common Warrant is exercisable immediately at an exercise price of $16.80 per share and will expire five years following the date of issuance. The Offering closed on December 9, 2022 and we received aggregate gross proceeds of approximately $4.1 million from the Offering.

The Offering was made under a registration statement on Form S-1 filed with the Securities and Exchange Commission (Registration No. 333-268038).

In connection with the Offering, the Company's directors and executive officers signed lock-up agreements by which they agreed not to sell or transfer any Common Stock without first obtaining the written consent of the Underwriter, subject to certain exceptions, for a period of 90 days after the date of the final prospectus relating to the Offering.

2023 Securities Purchase Agreement

On February 2, 2023, we entered into a definitive Securities Purchase Agreement (the "***Purchase Agreement***") with certain institutional investors (the "***Purchasers***"), pursuant to which the Company agreed to issue and sell in a registered direct offering (the "***Offering***"), priced "at-the-market" under the rules of The Nasdaq Stock Market, an aggregate of 297,619 shares (the "***Shares***") of common stock of the Company, par value $0.0001 per share (the "***Common Stock***"), at an offering price of $10.08 per share, for gross proceeds of approximately $3.0 million before the deduction of placement agent fees and offering expenses. The closing of the Offering occurred on February 6, 2023. The Shares were offered by the Company pursuant to a shelf registration statement on Form S-3 (File No. 333-269157), which was initially filed with the Securities and Exchange Commission (the "***Commission***") on January 9, 2023 and was declared effective by the Commission on January 17, 2023 (the "Registration Statement"), and a related prospectus.

In a concurrent private placement (the "***Private Placement***"), the Company issued to the Purchasers, for each share of Common Stock purchased in the Offering, a common warrant to purchase one share of Common Stock (the "***Common Warrants***"). The Common Warrants are exercisable immediately upon issuance and terminate five and one-half years following issuance. The Common Warrants have an exercise price of $8.58 per share and are exercisable to purchase an aggregate of up to 297,619 shares of Common Stock and expire on August 7, 2028. A holder of a Common Warrant will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or 9.99% at the election of the holder prior to the date of issuance) of the number of shares of Common Stock outstanding immediately after giving effect to such exercise (the "***Beneficial Ownership Limitation***"); provided, however, that upon 61 days' prior notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99%.

H.C. Wainwright & Co. acted as the exclusive placement agent (the "***Placement Agent***") for the Offering. We issued warrants (the "***Placement Agent Warrants***") to purchase up to 20,833 shares of Common Stock to the Placement Agent (including its designees). These warrants have an exercise price equal to $12.60 per share and are exercisable for five years from the commencement of sales in the Offering. The Common Warrants and Placement Agent Warrants and the shares of our Common Stock issuable upon the exercise of the Common Warrants and Placement Agent Warrants are not being registered under the Securities Act of 1933, as amended (the "***Securities Act***"), are not being offered pursuant to the Registration Statement, and are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b).

In the Purchase Agreement, we agreed not to issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock for a period of 30 days following the closing of the Offering. Our officers and directors agreed, subject to limited exceptions, for a period of 90 days after the closing of the Offering, to not offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of, directly or indirectly, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Securities Exchange Act of 1934, as amended, with respect to, any shares of Common Stock or securities convertible, exchangeable or exercisable into, shares of Common Stock beneficially owned, held or thereafter acquired by them.

The closing of the Offering and the Private Placement was subject to satisfaction of customary closing conditions set forth in the Purchase Agreement. The representations, warranties and covenants contained in the Purchase Agreement were made solely for the benefit of the parties to the Purchase Agreement. In addition, such representations, warranties and covenants (i) are intended as a way of allocating the risk between the parties to the Purchase Agreement and not as statements of fact, and (ii) may apply standards of materiality in a way that is different from what may be viewed as material by stockholders of, or other investors in, the Company. Accordingly, the Purchase Agreement is filed with this report only to provide investors with information regarding the terms of transaction, and not to provide investors with any other factual information regarding the Company. Moreover, information concerning the subject matter of the representations and warranties may change after the date of the Purchase Agreement, which subsequent information may or may not be fully reflected in public disclosures.

Components of Our Operating Results

Revenue

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

We have received funding under federal grants from the NIH through NIDA. In September 2018, we were awarded 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 CROs that are primarily engaged in the oversight and conduct of our drug discovery efforts and preclinical studies, clinical trials and CMOs that are primarily engaged to provide preclinical and clinical drug substance and product for our research and development programs;
- other costs related to acquiring and manufacturing materials in connection with our drug discovery efforts and preclinical studies and clinical trial materials, including manufacturing validation batches, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- payments made in cash or equity securities under third-party licensing, acquisition and option agreements;
- employee-related expenses, including salaries and benefits, travel and stock-based compensation expense for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements; and
- allocated facilities-related costs, depreciation and other expenses, which include rent and utilities.

We recognize external development costs as incurred. Any advance payments 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 manage 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 remain elevated as we continue our existing, and commence 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, subject to our ability to obtain financing. We also expect 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 remain elevated. In addition, we may incur additional expenses related to milestone and royalty payments payable to third parties with whom we may enter 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, legal, information technology, and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as insurance costs and professional fees for legal, patent, consulting, investor and public relations, accounting and audit services. We expense general and administrative costs as incurred.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support the continued development of our product candidates, subject to our ability to obtain financing. 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. 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)

Loss on issuance of convertible notes

We elected the fair value option to account for the 2021 Notes as we believe the fair value option provides users of the financial statements with greater ability to estimate the outcome of future events as facts and circumstances change, particularly with respect to changes in the fair value of the common stock underlying the conversion option. 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 upon initial recognition and at the balance sheet date. We use a discounted cash flow model and a Monte Carlo simulation to estimate the fair value of the notes, both of which rely on unobservable Level 3 inputs. The loss on issuance of convertible notes represents the difference between the gross proceeds received and the calculated fair value on the issuance date of the notes.

Issuance costs for convertible notes

The issuance costs for convertible notes represent the original issue discount (expensed immediately due to the initial recognition at fair value of both the 2021 and 2022 Notes noted above), legal and accounting fees incurred in connection with the issuance of the 2021 and 2022 Notes.

Change in fair value of convertible notes

We elected the fair value option to account for the 2021 Notes as we believe the fair value option provides users of the financial statements with greater ability to estimate the outcome of future events as facts and circumstances change, particularly with respect to changes in the fair value of the common stock underlying the conversion option. The 2022 Notes are accounted for under ASC 480 – *Distinguishing Liabilities from Equity,* due to share settlement features contained within the notes. We use a discounted cash flow model and a Monte Carlo simulation 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.

Issuance 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 at issuance. This represents the immediate expense upon initial recognition of the liability that is included in the statement of operations. The liability is subsequently remeasured each reporting period as described further below.

Change in fair value of liability classified warrants

We use a Black-Scholes option pricing model to estimate the fair value of the liability classified 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 occurred, we calculated 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. Interest expense related to the 2021 Notes and 2022 Notes is included in the estimate of fair value of the convertible notes.

Provision for Income Taxes

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

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or our tax returns. Deferred tax assets and liabilities are determined based on difference between the financial statement carrying amounts and tax bases of existing assets and liabilities and for loss and credit carryforwards, which are measured using the enacted tax rates and laws in effect in the years in which the differences are expected to reverse. The realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of March 31, 2023 and December 31, 2022, we continue to maintain a full valuation allowance against all of our deferred tax assets based on our evaluation of all available evidence.

Beginning in 2022, the Tax Cuts and Jobs Act, or the Tax Act, eliminated the option to deduct research and development expenditures currently and requires taxpayers to capitalize and amortize them over five or fifteen years pursuant to Internal Revenue Code Section 174. This has not impacted our effective tax rate or our cash tax payable in 2023; however, if the requirement to capitalize Section 174 expenditures is not modified, it may also impact our effective tax rate and our cash tax liability in future years.

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 2019 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 March 31, 2023 and 2022:

	Three Months Ended March 31,		
	2023	**2022**	**Change**
Federal grants	$ 789,635	$ 603,098	$ 186,537
Operating expenses:			
Research and development	1,796,015	3,140,096	(1,344,081)
General and administrative	1,554,855	2,265,806	(710,951)
Total operating expenses	3,350,870	5,405,902	(2,055,032)
Loss from operations	(2,561,235)	(4,802,804)	2,241,569
Other income (expense):			
Change in fair value of convertible notes	146,479	2,767,178	(2,620,699)
Change in fair value of liability classified warrants	219,028	2,794,398	(2,575,370)
Loss on debt conversions	-	(1,702,642)	1,702,642
Interest expense	(1,497)	(15,021)	13,524
Other income and expense, net	5,419	7,966	(2,547)
Total other income/(expenses), net	369,429	3,851,879	(3,482,450)
Net loss	(2,191,806)	(950,925)	(1,240,881)
Net loss attributable to noncontrolling interests	(3,941)	182	(4,123)
Deemed dividend related to warrants down round provision	8,309	715,579	(707,270)
Net loss attributable to common stockholders	$ (2,196,174)	$ (1,666,686)	$ (529,488)

Federal grant funding

Funding from federal grants for the three months ended March 31, 2023 and 2022 totaled $0.8 million and $0.6 million, respectively. The difference is due to the timing of research activities eligible for funding. We expect funding from federal grants to fluctuate 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 March 31, 2023 and 2022 were $1.8 million and $3.1 million, respectively, representing a decrease of $1.3 million. The decrease was primarily the result of changes in timing of external research and development costs related to clinical and pre-clinical programs for PF614 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 March 31, 2023 and 2022 were $1.6 million and $2.3 million, respectively, representing a decrease of $0.7 million. The decrease was primarily a result of reduced stock-based compensation, liability insurance and employee bonus expenses in the 2023 period. We expect future general and administrative expenses to approximate current levels.

Other income and expense

Changes in fair value of the 2022 Notes (outstanding in 2023) and the 2021 Notes (outstanding in 2022) are due to the significant fluctuations in the Company's share price as well as the balance outstanding for the respective Notes for the relevant period. The change in fair value of liability classified warrants for the three months ended March 31, 2023 are primarily the result of the warrants outstanding for both the 2021 Notes and 2022 Notes compared to only changes related to the warrants associated with the 2021 Notes in the prior period, as well as fluctuations associated with the Company's decreasing share price. Loss on debt conversions is driven by the difference between the conversion price of the 2021 Notes and the average of the high and low stock price on the date of conversion. There was no corresponding activity in the 2023 period associated with the 2022 Notes due to the accounting under ASC 480.

Liquidity and capital resources

Sources of liquidity and capital

As of March 31, 2023, we had $1.4 million of cash and cash equivalents. On May 12, 2023, we completed a public offering with gross proceeds of $7.0 million, before deducting placement agent fees and other offering expenses, for the sale of an aggregate of 1.8 million shares of common stock (or pre-funded warrants in lieu thereof) at a combined offering price of $3.887 per share, including warrants to purchase up to 3.6 million shares at an exercise price of $3.637 per share. 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 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.

We have funded our operations to date primarily with proceeds from the sale of common equity, funding under federal research grants and borrowings under convertible promissory notes. To fund future operations, we will need to raise additional capital. The amount and timing of future funding requirements will depend on many factors, including the timing and results of our ongoing research and development efforts and related general and administrative support. We anticipate that we will fund our operations through public or private equity or debt financings or other sources, which may include potential collaboration agreements with third parties. We cannot make assurances that anticipated additional financing will be available to us on favorable terms, if at all, or that we will enter into any collaborations.

Remaining funding under two approved federal research grants totaled $3.9 million at March 31, 2023 and is expected to be utilized by 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 must 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.

We have not used the GEM facility to date. 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 (expires on July 1, 2024). 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 may not be able to utilize the facility before it expires. Our ability to utilize this share subscription facility is restricted while financing commitments to which we are subject remain 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 3,838 shares of common stock transferred from related parties in July 2022. The commitment fee for the second tranche, which was equal to the remaining 33% of the commitment fee, or $400,000, was paid in January 2023 through the issuance of 44,444 shares of registered common stock.

Additionally, we issued a warrant with a 36-month term at the closing of the Merger granting GEM Global the right to purchase 4,608 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 $2,402.40, which was the closing bid price for such common stock on the first day of trading on Nasdaq. The strike price was reduced to $8.58 per share as of March 31, 2023 because of a pricing adjustment per the GEM Agreement which is reflected on the consolidated statement of operations as a deemed dividend. The warrant can be exercised on a cashless basis in part or in whole at any time during the term. Any failure by us to timely transfer the shares under the warrant pursuant to GEM Global's exercise will entitle GEM Global to compensation in addition to other remedies. The number of shares underlying the warrant as well as the strike price is subject to adjustments for recapitalizations, reorganizations, change of control, stock split, stock dividend, reverse stock splits, and issuances of additional common shares at a price per share less than the exercise price.

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 4,512 shares of the Company's common stock in the aggregate at a current exercise price of $187.20 per share. The 2021 Notes were satisfied on October 11, 2022.

On June 30, 2022, we entered into 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 38,894 shares of the Company's common stock in the aggregate at a current exercise price of $24.07 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 At March 31, 2023, the outstanding principal of the Notes were satisfied and a remaining balance of $0.6 million owed to the institutional investors was reflected in Accrued Expenses and Other Liabilities.

Cash flows

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

	Three Months Ended March 31,	
	2023	**2022**
Net cash used in operating activities	$ (3,606,919)	$ (3,437,014)
Net cash provided by investing activities	-	4,500
Net cash provided by (used in) financing activities	1,874,982	(391,270)
Net decrease in cash and cash equivalents	$ (1,731,937)	$ (3,823,784)

Operating activities

During the three months ended March 31, 2023 and 2022, we used cash in operating activities of $3.6 million and $3.4 million, respectively. The increase primarily resulted from the timing of vendor invoicing and payments.

Investing activities

During the three months ended March 31, 2023, there were no investing activities.

Financing activities

During the three months ended March 31, 2023, net cash provided by financing activities was $1.9 million, primarily consisting of proceeds from 2023 Offering, net of transaction costs and the repayment of financed insurance premiums and cash payment of convertible notes. During the three months ended March 31, 2022, net cash used in financing activities was $0.4 million, primarily consisting of repayment of financed insurance premiums.

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, 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. 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. As of March 31, 2023, had an accumulated deficit of $113.1 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future.

Without the certainty of available proceeds through the GEM facility, or capital raised through other financing transactions, existing cash resources are not sufficient to allow us to fund current planned operations through the next 12 months following the filing of this Quarterly Report on Form 10-Q, 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 audited consolidated financial statements included in our 2022 Annual Report on Form 10K, 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. Many 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 adjust 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 using the accelerated attribution method 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 with performance-based vesting conditions is recognized based on the grant date fair value over the requisite service period using the accelerated attribution method over the requisite service period to the extent achievement of the performance condition is probable.

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

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

Fair Value of Liabilities

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

In July and August 2022, the Company issued the 2022 Notes. 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 simulation, 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 simulation.

We issued warrants in connection with the issuance of both the 2021 and 2022 Notes. The warrants were liability classified due to certain cash settlement features. 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.

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 Ensysce's financial position and results of operations is disclosed in Note 3 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our cash and cash equivalents as of March 31, 2023 consisted of cash and a money market fund account. Because of the short-term nature of our money market fund, a sudden change in market interest rates would not be expected to have a material impact on our financial position or results of operations.

Inflation Risk

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a–15€ and 15d-15(e)) as of March 31, 2023. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were not effective as of March 31, 2023 due to the material weaknesses in our internal controls over financial reporting described below. Notwithstanding these material weaknesses, management has concluded that our financial statements included in this Quarterly Report on Form 10-Q are fairly stated in all material respects in accordance with GAAP for each of the periods presented therein.

Material Weaknesses and Remediation Plan

In connection with the preparation of our consolidated financial statements for the years ended December 31, 2022 and 2021, and our unaudited interim consolidated financial statements for the three months ended March 31, 2023 and 2022, 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.

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

Changes in Internal Control Over Financial Reporting

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

While we attempt to identify, manage and mitigate risks and uncertainties associated with our business to the extent practical, under the circumstances, some level of risk and uncertainty will always be present. Part I, Item 1A. Risk Factors of our 2022 Annual Report on Form 10-K includes a detailed discussion of our risk factors. Those risks and uncertainties have the potential to materially affect our financial condition and results of operations. The risks set forth in the following additional risk factors have the potential to materially affect our financial condition and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits.

The following exhibits are filed as part of this report:

Exhibit Number	Description
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ENSYSCE BIOSCIENCES, INC.

Date: May 15, 2023

/s/ David Humphrey
David Humphrey
Chief Financial Officer, Secretary and Treasurer

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lynn Kirkpatrick, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ensysce Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2023

/s/ Lynn Kirkpatrick
Name: Lynn Kirkpatrick
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Humphrey, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ensysce Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2023

/s/ David Humphrey
Name: David Humphrey
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Ensysce Biosciences, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lynn Kirkpatrick, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: May 15, 2023

/s/ Lynn Kirkpatrick
Lynn Kirkpatrick
Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Report and shall not be deemed "filed" by the Company with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Ensysce Biosciences, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Humphrey, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Dated: May 15, 2023

/s/ David Humphrey
David Humphrey
Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Report and shall not be deemed "filed" by the Company with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.