

**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 September 30, 2022

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
Warrants to purchase one share of Common Stock	ENSCW	OTC Pink Open Market

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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 November 7, 2022, the registrant had 2,841,091 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:

- the risk that our lead product candidate PF614 and PF614-MPAR™ may not be successful in limiting or impeding abuse, overdose, or misuse or providing additional safety upon commercialization;
- reliance by us on third-party contract research organizations, or CROs, for its research and development activities and clinical trials;
- the need for substantial additional funding to complete the development and commercialization of our product candidates;
- the risk 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 its product candidates;
- the risk that our product candidates may not be beneficial to patients or successfully commercialized;
- the risk that we have overestimated the size of the target market, patients’ willingness to try new therapies, and the willingness of physicians to prescribe these therapies;
- effects of competition;
- the risk that third parties on which we depend for laboratory, clinical development, manufacturing, and other critical services will fail to perform satisfactorily;
- the risk that our business, operations, clinical development plans and timelines, and supply chain could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic;
- the risk that we will be unable to obtain and maintain sufficient intellectual property protection for its investigational products or will infringe the intellectual property protection of others;
- the loss of key members of our management team;
- changes in our regulatory environment;
- the ability to attract and retain key scientific, medical, commercial, or management personnel;
- changes in our industry;
- our ability to remediate any material weaknesses or maintain effective internal controls over financial reporting;
- the risk that our common stock will be suspended from trading on Nasdaq;
- the ability to meet and maintain applicable listing standards of the Nasdaq; and
- other factors disclosed in this Quarterly Report on Form 10-Q.

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 Ensyesce. There can be no assurance that future developments affecting Ensyesce will be those that Ensyesce has anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Ensyesce’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, 2021 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 Ensyesce. Ensyesce 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
2022 Notes	The senior secured convertible promissory notes in the aggregate original principal amount of \$8.48 million, sold in two closings on July 1, 2022, and August 9, 2022, respectively, pursuant to the Securities Purchase Agreement entered into on June 30, 2022
2021 Omnibus Incentive Plan	Ensysce Biosciences, Inc. Amended and Restated 2021 Omnibus Incentive Plan
Aggregate Limit	Up to \$60 million of gross proceeds with respect to the GEM Agreement
ASC 606	Accounting Standards Codification Topic 606, <i>Revenue from Contracts with Customers</i>
ASC 740	Accounting Standards Codification Topic 740, <i>Income Taxes</i>
ASC 820	Accounting Standards Codification Topic 820, <i>Fair Value Measurements</i>
Board	Board of directors of Ensysce, or a committee thereof, as applicable
Business Combination	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.
CMOs	Contract manufacturing organizations
Company	Ensysce Biosciences, Inc. and its consolidated subsidiaries
COVID-19	Novel coronavirus disease
CROs	Contract research organizations
EBIR	A clinical stage pharmaceutical company (formerly Covistat, Inc.) that is developing a compound utilized in the Company's overdose protection program for the treatment of COVID-19 and a 79.2%-owned subsidiary of the Company
Ensysce	Ensysce Biosciences, Inc.
Exchange Act	Securities Exchange Act of 1934
FDA	United States Food and Drug Administration
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
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
GYBL	GEM Yield Bahamas Limited
IND	Investigational New Drug
IRB	Institutional Review Board
JOBS Act	Jumpstart Our Business Startups Act of 2012
LACQ	Leisure Acquisition Corp., a Delaware Corporation
Merger 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	Multi-Pill Abuse Resistance
MPAR Grant	Research and development grant related to the development of its MPAR <sup>TM</sup> overdose prevention technology awarded to the Company by NIH through NIDA in September 2018
Nasdaq	Nasdaq Stock Market LLC
NIDA	National Institute of Drug Abuse
NIH	National Institutes of Health
ODU Grant	Research and development grant related to the development of its TAAP/MPAR <sup>TM</sup> abuse deterrent technology for Opioid Use Disorder awarded to the Company by NIH/NIDA in September 2019
Reverse Stock Split	The reclassification and combination of all shares of our common stock outstanding at a ratio of 1-for-20 approved by our stockholders at the Special Meeting held on September 8, 2022 and effective on October 28, 2022
SEC	U.S. Securities and Exchange Commission
Securities Act	Securities Act of 1933
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
TAAP	Trypsin Activated Abuse Protection

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**PART I—FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

**ENSYSCE BIOSCIENCES, INC.  
CONSOLIDATED BALANCE SHEETS**

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

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

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

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

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

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

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

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

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



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

	<b>Nine Months Ended September 30,</b>	
	<b>2022</b>	<b>2021</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (18,729,609)	\$ (19,108,777)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	-	151
Gain on sale of asset	(4,500)	-
Accrued interest	57,536	336,851
Accretion of discounts on promissory notes	-	945,969
Change in fair value of derivative liabilities	-	(673,314)
Change in fair value of liability classified warrants	(5,626,130)	-
Loss on issuance of convertible notes	3,609,944	-
Change in fair value of convertible notes	(6,169,929)	(1,071,099)
Loss on extinguishment of debt	-	347,566
Stock-based compensation	855,160	105,026
Issuance of warrants for share subscription facility	-	11,565,472
Issuance of liability classified warrants	3,737,371	620,718
Issuance costs for convertible notes	946,085	800,158
Commitment fee for share subscription facility	-	1,124,292
Warrant modification	-	56,590
Lease cost	(63)	(1,838)
Loss on debt conversions	4,000,155	-
Changes in operating assets and liabilities:		
Unbilled receivable	300,908	(86,867)
Prepaid expenses and other assets	475,499	(683,492)
Accounts payable	984,410	(1,252,740)
Accrued expenses and other liabilities	971,344	2,500,970
Net cash used in operating activities	(14,591,819)	(4,474,364)
<b>Cash flows from investing activities:</b>		
Proceeds from sale of asset	4,500	-
Net cash provided by investing activities	4,500	-
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of convertible notes, net	7,533,915	4,549,842
Proceeds from issuance of promissory notes to related parties	-	350,000
Proceeds from exercise of stock options	-	262,862
Repayment of promissory notes	-	(467,774)
Repayments of convertible notes	(265,812)	-
Proceeds from issuance of common stock for business combination, net of transaction costs	-	6,626,312
Repayment of financed insurance premiums	(442,439)	(195,420)
Net cash (used in) provided by financing activities	6,825,664	11,125,822
Increase in cash and cash equivalents	(7,761,655)	6,651,458
<b>Cash and cash equivalents beginning of period</b>	12,264,736	194,214
<b>Cash and cash equivalents end of period</b>	<u>\$ 4,503,081</u>	<u>\$ 6,845,672</u>
<b>Supplemental cash flow information:</b>		
Income tax payments	\$ 1,600	\$ 1,600
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Stock-based compensation	\$ 1,742,478	\$ -
Conversions of convertible notes and accrued interest into common stock	\$ 13,879,535	\$ 5,696,703
Payable to related parties	\$ 800,000	\$ -
Net assets acquired in business combination	\$ -	\$ 1,068,950
Financed insurance premiums	\$ 399,949	\$ 867,300
Share subscription facility transaction costs	\$ -	\$ 12,689,764
Deemed dividend related to warrants down round provision	\$ 881,598	\$ -

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

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

**NOTE 1 – ORGANIZATION AND PRINCIPAL ACTIVITIES**

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

On January 31, 2021, LACQ entered into the Merger Agreement with Former Ensysce and Merger Sub. Pursuant to the Merger Agreement, on June 30, 2021 (the “Closing Date”), Merger Sub was merged with and into Former Ensysce, with Former Ensysce surviving the merger (“Merger”). In connection with the closing of the Business Combination on the Closing Date (the “Closing”), Former Ensysce became a wholly-owned subsidiary of LACQ and the stockholders of Former Ensysce, as of immediately prior to the effective time of the Merger, received shares of LACQ and hold a portion of the shares of Common Stock, par value \$0.0001 per share (the “Common Stock”), of LACQ.

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

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

In June 2020, the Company commenced an initiative to develop a therapeutic for the treatment of certain coronavirus infections through the formation of a separate entity, Covistat, Inc., a Delaware corporation. Pursuant to the articles of incorporation, Covistat was authorized to issue 1,000,000 shares of common stock, \$0.001 par value per share, and 100,000 shares of preferred stock, \$0.001 par value per share. In August 2022, Covistat was renamed EBIR, Inc. Ensysce is a 79.2% stockholder in EBIR, with 19.8% and 1.0% of the shares held by certain key personnel of the Company and an unrelated party, respectively. EBIR’s emphasis is now on developing one or more compounds utilized in Ensysce’s overdose protection program for the treatment of respiratory diseases.

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

**NOTE 2 - BASIS OF PRESENTATION**

The consolidated financial statements have been prepared in accordance with GAAP and pursuant to the rules and regulations of the SEC. The consolidated financial statements include the accounts of Ensysce Biosciences, Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated in the consolidation.

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

#### ***Reverse Stock Split***

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

#### ***Business Combination***

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

#### ***Going Concern***

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

The Company has not generated any product revenue and had an accumulated deficit of \$105.4 million at September 30, 2022. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. Product development activities, clinical and pre-clinical testing, and commercialization of the Company's product candidates are necessary to develop the Company's products and will require significant additional financing. There can be no assurance the Company will be able to obtain such funds. These matters, among others, raise substantial doubt about the Company's ability to continue as a going concern.

In December 2020, the Company executed the GEM Agreement. Under the agreement, the investor agreed to provide the Company with a share subscription facility of up to \$60.0 million for a 36-month term following the public listing of the Company's common stock. The Company controls the timing and maximum amount of drawdown under this facility and has no minimum drawdown obligation. The investor will pay, in cash, a per-share amount equal to 90% of the average daily closing price of the Company's stock during the 30 consecutive trading days prior to the issuance of a draw notice, which shall not exceed 400% of the average trading volume for the 30 trading days immediately preceding the draw down date. On June 30, 2021, the Company consummated the Business Combination, resulting in the Company's shares becoming publicly listed on Nasdaq on July 2, 2021. Concurrent with the public listing of the Company's shares, the Company issued to the investor 55,306 warrants with a five-year term to purchase common stock of Ensysce at an exercise price of \$200.20 per share (Note 8). The Company is required to pay a commitment fee to the investor of \$1.2 million with \$0.8 million due on the first anniversary of the public listing date and \$0.4 million due on the 18-month anniversary of the public listing date. The first \$0.8 million of the commitment fee was paid in July 2022 in common stock of the Company (Note 10) and the remaining \$0.4 million due in January 2023 may be paid from the proceeds of a draw against the facility or in freely tradable common stock of the Company.

In September 2021, the Company entered into a \$15.9 million convertible note financing agreement with institutional investors (the “2021 Notes”) (See Note 7 for additional information). In July and August 2022, the Company received funding under a \$8.48 million convertible note financing agreement with the same institutional investors (the “2022 Notes”) (Note 7). The agreements limit the Company’s ability to execute certain debt and equity financings, including under the GEM Agreement, while the convertible notes are outstanding. Without the availability of proceeds through the GEM Agreement, existing cash resources are not sufficient to fund current planned operations. While the Company believes in the viability of its strategy to ultimately realize revenues and in its ability to raise additional funds, management cannot be certain that additional funding will be available on acceptable terms, or at all. The Company’s ability to continue as a going concern is dependent upon its ability to obtain adequate financing and achieve profitable operations. As a result, these plans do not alleviate substantial doubt about the Company’s ability to continue as a going concern for a period of 12 months following the date these consolidated financial statements were issued.

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

### **NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

#### ***Use of Estimates and Assumptions***

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

#### ***Cash and Cash Equivalents***

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

#### ***Concentrations of credit risk and off-balance sheet risk***

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

#### ***Property and Equipment***

Property and equipment include office and laboratory equipment that is recorded at cost and depreciated using the straight-line method over the estimated useful lives of five to six years. No depreciation expense was recognized for the three and nine months ended September 30, 2022. Depreciation expense of \$50 and \$151 was recognized for the three and nine months ended September 30, 2021. Depreciation expense is classified in general and administrative expense in the accompanying consolidated statements of operations.

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. For long-lived assets to be held and used, the Company will recognize an impairment loss only if the carrying amount is not recoverable through its undiscounted cash flows and measure any impairment loss based on the difference between the carrying amount and estimated fair value. There were no such losses for the three and nine months ended September 30, 2022 and 2021.

## ***Derivative Financial Instruments***

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

## ***Fair Value Measurement***

ASC 820, *Fair Value Measurements*, ("ASC 820") provides guidance on the development and disclosure of fair value measurements. Pursuant to ASC 820, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

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

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.
- Level 3: Unobservable inputs which are supported by little, or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

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

As of September 30, 2022 and December 31, 2021, the recorded values of cash and cash equivalents, prepaid expenses, accounts payable, and accrued expenses and other liabilities approximate their fair values due to the short-term nature of these items.

## ***2021 Notes***

In 2021 the Company issued convertible notes with a face value of \$15.9 million. The Company elected the fair value option to account for the convertible notes as it believes the fair value option provides users of the financial statements with greater ability to estimate the outcome of future events as facts and circumstances change, particularly with respect to changes in the fair value of the common stock underlying the conversion option and redemption feature. The fair value estimate of the 2021 Notes was based on a discounted cash flow model and a Monte Carlo model, which represent Level 3 measurements. Significant assumptions include the discount rate used in the discounted cash flow model and the expected premium for conversion used in the Monte Carlo model. Changes in the fair value of the notes are recognized in other income (expense) for each reporting period. Refer to Note 7 for details of the terms and conditions of the 2021 Notes.

## ***2022 Notes***

In July 2022 the Company issued convertible notes with a face value of \$8.5 million. The 2022 Notes are accounted for under ASC 480 – *Distinguishing Liabilities from Equity*, due to share settlement features contained within the notes. As a result, the 2022 Notes are recorded as liabilities at fair value at the balance sheet date with changes in the fair value of the notes recognized in other income (expense) for each reporting period. The fair value estimate of the 2022 Notes was based on a discounted cash flow model and a Monte Carlo model, which represent Level 3 measurements. Significant assumptions include the discount rate used in the discounted cash flow model and the expected premium for conversion used in the Monte Carlo model. Refer to Note 7 for details of the terms and conditions of the 2022 Notes.

## Warrants

In 2021 the Company issued liability classified warrants in connection with the issuance of the 2021 Notes. In 2022 the Company issued liability classified warrants in connection with the issuance of the 2022 Notes. The warrants were liability classified due to certain cash settlement features and included in “Other long-term liabilities” on the consolidated balance sheets. The Company uses a Black Scholes model to estimate the fair value of the warrants. Changes in the fair value of the warrants are recognized in other income (expense) for each reporting period. Refer to Note 8 for details of the warrants.

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

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

  

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

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

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

## Federal Grants

In September 2018, the National Institutes of Health (“NIH”) through the National Institute on Drug Abuse awarded the Company a research and development grant related to the development of its MPAR<sup>TM</sup> overdose prevention technology (the “MPAR Grant”). The total approved budget for the initial two-year period was approximately \$5.4 million (\$3.2 million and \$2.2 million in years 1 and 2, respectively) of which the Company must contribute \$1.1 million in the first year of the grant. In August 2019, the grant was amended such that the approved budget for the two-year period decreased to approximately \$5.1 million (\$2.1 million and \$3.0 million in years 1 and 2, respectively). In June 2021, the Company received a Notice of Award for an additional \$2.8 million of funding in year 3 under the MPAR Grant beginning July 1, 2021. In June 2022, the Company received a Notice of Award for an additional \$2.8 million of funding in year 4 under the MPAR Grant from July 1, 2022 through June 30, 2023. This brings total funding under this grant to approximately \$10.8 million.

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

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

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

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

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

#### ***Immaterial Correction of an Error Adjusted in Prior Quarter***

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

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

#### ***Research and Development Costs***

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

#### ***General and Administrative Expenses***

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

#### ***Stock-based Compensation***

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

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model. The assumptions used in calculating the fair value of stock-based awards represent management’s best estimates and involve inherent uncertainties and the application of management’s judgment. For the three and nine months ended September 30, 2022 and 2021, stock-based compensation costs are recorded in general and administrative expenses and research and development expenses in the consolidated statements of operations.

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

## Income Taxes

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

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

## Earnings per Share

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options	350,995	222,203	328,538	225,833
Warrants	1,054,544	1,000,953	1,054,544	335,531
Total	1,405,539	1,223,156	1,383,082	561,364



### ***Recently Issued Accounting Pronouncements***

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (“ASU 2019-12”), which simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The guidance is effective for fiscal years beginning after December 31, 2021 and interim periods within that year. On January 1, 2022, the Company adopted ASU 2019-12 and the adoption did not have a significant impact on the consolidated financial statements.

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

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

**NOTE 4 – PREPAID EXPENSES AND OTHER CURRENT ASSETS**

Prepaid expenses and other current assets consisted of the following:

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

**NOTE 5 – ACCRUED EXPENSES AND OTHER LIABILITIES**

Accrued expenses and other liabilities consisted of the following:

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

Other long-term liabilities consisted of the following:

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

**NOTE 6 – COMMITMENTS AND CONTINGENCIES*****Purchase Commitments***

As of September 30, 2022, the Company's commitments included an estimated \$25.7 million related to the Company's open purchase orders and contractual obligations that occurred in the ordinary course of business, including commitments with contract research organizations for multi-year pre-clinical and clinical research studies. Although open purchase orders are considered enforceable and legally binding, the terms generally allow the Company the option to cancel, reschedule, and adjust its requirements based on its business needs prior to the delivery of goods or the performance of services.

***Litigation***

As of September 30, 2022 and December 31, 2021, there were no pending legal proceedings against the Company that are expected to have a material adverse effect on cash flows, financial condition or results of operations. From time to time, the Company could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. Periodically, the Company reviews the status of significant matters, if any exist, and assesses its potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount can be estimated, the Company accrues a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict. Because of such uncertainties, accruals are based on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation.

### ***Lease***

In August 2020, the Company entered into an agreement to lease office space. The original lease commencement date was October 1, 2020 and was subsequently amended to extend the term of the lease through October 31, 2023 with no option to renew. The amendment resulted in a modification of the lease under ASC 842 and the Company remeasured the lease liability as of the amendment date.

As of September 30, 2022, the future lease payments totaled \$35,403.

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

### ***Compensation Subject to Shareholder Approval***

In July 2021, the Company engaged two consultants to perform certain public and investor relations services in consideration for warrants to purchase 25,000 shares of common stock with a five-year term and an exercise price of \$125.60 each, 2,500 shares of common stock each, and 10,000 restricted stock units each. The restricted stock units vested over one year with 50% of the vesting contingent upon certain market conditions. These equity awards were contingent upon shareholder approval of an amended and restated 2021 Omnibus Plan at a special shareholder meeting in January 2022, at which time the warrants were replaced by non-qualified stock options with similar terms. As the original terms of the awards did not satisfy the grant date criteria for an equity award, as of December 31, 2021, the Company recorded a liability \$1,342,479 to reflect the estimated value of services received during the period. On February 14, 2022, the equity awards were granted, and the Company reclassified the outstanding liability to stockholders' equity (See Note 9 for additional details of the Company's stock-based compensation).

### **NOTE 7 – NOTES PAYABLE**

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

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

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

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

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

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

#### 2021 Notes

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

The proceeds of the 2021 Notes shall be used for working capital purposes subject to certain customary restrictions and secured by the Company’s rights to its patents and licenses. The Company may not issue any additional debt or equity without the prior written consent of the holders.

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

The Company elected to apply the fair value option to the measurement of the 2021 Notes. The total initial fair value of the debt at issuance was \$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. After multiple conversions (at original contract terms and at amended reduced conversion prices) since issuance, the Company reflected the remaining balance due as of September 30, 2022 and recognized a change in fair value of convertible notes of \$45,329 (loss) for the three-month period then ended and a change in fair value of convertible notes of \$2.7 million (gain) for the nine-month period ended September 30, 2022 primarily due to reductions in the Company’s stock price. The September 30, 2022 fair value measurement includes the assumption of accrued interest and interest expense (at the stated rate plus an 8% cash settlement premium) and thus a separate amount is not reflected on the consolidated statements of operations. If presented separately, the amount of interest expense after consideration of the conversions would be \$39,847 and \$0.2 million for the three- and nine-month periods ended September 30, 2022, respectively.

The 2021 Notes may be converted into the Company’s common stock at the option of the holder in whole or in part at the conversion price of \$117.40, subject to a beneficial ownership limitation of 4.99% (subject to adjustment). The Company must reserve sufficient shares of authorized common stock to effect the conversion of the 2021 Notes and payment of interest. The shares were registered for public resale under a registration statement.

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

Beginning January 1, 2022 for the First Closing, and February 1, 2022 for the Second Closing, and the first of each subsequent month, terminating upon the full redemption of the 2021 Notes (each a “Monthly Redemption Date”), the Company shall redeem the Monthly Redemption Amount (defined below), payable in cash or shares. The number of shares to be settled shall be based on a conversion price equal to the lesser of (a) \$117.40 and (b) 92% of the average of the three lowest volume-weighted average prices (“VWAP”) during the 10 consecutive trading days prior to the applicable Monthly Redemption Date. The Company may not pay the Monthly Redemption Amount in shares unless the applicable conversion price is greater than or equal to \$15.60 and the Company has been in compliance with customary requirements under the agreement, unless waived in writing by the holder. If the applicable conversion price is less than \$15.60 at the time of the Monthly Redemption Date the Company will be required to fund the difference in cash. During the period ended September 30, 2022, the Company paid \$265,812 to fund such differences in cash (reducing the outstanding principal balance of the 2021 Notes).

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

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

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

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

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

## 2022 Notes

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

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

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

The September 30, 2022 fair value measurement includes the assumption of accrued interest and interest expense (at the stated rate plus an 8% cash settlement premium) and thus a separate amount is not reflected on the consolidated statements of operations. If presented separately, the amount of interest expense after consideration of the conversions would be \$0.1 million for the three- and nine-month periods ended September 30, 2022.

The 2022 Notes are convertible into common stock, at a per share conversion price equal to \$10.90, a 10% premium to the average price of the common stock for the three trading days prior to the first closing. Under the Notes, commencing on September 29, 2022 and continuing monthly on the first day of each month beginning November 2, 2022, the Company is obligated to redeem one fifteenth (1/15<sup>th</sup>) of the original principal amount under the applicable Note, plus accrued but unpaid interest. The Company may elect to pay all or part of the redemption amount in cash with a premium of eight percent or in conversion shares of common stock based on a conversion price equal to the lesser of (i) the conversion price and (ii) 92% of the average of the three lowest VWAPs (as defined) during the ten consecutive trading days ending on the trading day that is immediately prior to the applicable redemption date, but in no event may the Company pay the redemption amount in conversion shares of common stock unless the conversion price is at least equal to \$2.006 and the Company has been in compliance with customary requirements under the agreement, unless waived in writing by the holder.

In connection with each of the first and second closings of the 2022 Notes the Company also issued warrants to purchase 233,395 shares of the Company's common stock. The warrants have an exercise price of \$14.17, a 30% premium to the conversion price, and are exercisable 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 \$15.60.

The proceeds of the 2022 Notes will be used for working capital purposes subject to certain customary restrictions are secured by the Company's rights to its patents and licenses. The Company is restricted from issuing certain additional debt or equity without the prior written consent of the holders for certain specified periods set forth in the 2022 Notes. If, at any time while the 2022 Notes are outstanding, the Company carries out one or more capital raises in excess of \$5.0 million, the holder has the right to require the Company to use up to 20% of the gross proceeds of such transaction to redeem all or a portion of the convertible notes for an amount in cash equal to the cash Mandatory Redemption Amount (i.e., 108% of outstanding principal and unpaid interest).

The 2022 Notes mature on December 29, 2023 and February 7, 2024, for the first and second closings, respectively. The notes bear interest at a rate of 6% per annum, in addition to an original issue discount of 6%. The interest may be settled in cash or shares at the option of the Company and is payable together with monthly redemptions of the outstanding principal amount of the debt.

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

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

#### *Financed insurance premiums*

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

#### **NOTE 8 - STOCKHOLDERS' EQUITY**

In June 2021, in connection with the Business Combination, the Company amended and restated its Certificate of Incorporation to authorize 150,000,000 shares of common stock and 1,500,000 shares of preferred stock, both with par value equal to \$0.0001. In September 2022, the Company amended and restated its Certificate of Incorporation to authorize shares up to a total of 250,000,000 shares of common stock. As of September 30, 2022 and December 31, 2021, there were no shares of preferred stock issued and outstanding.

#### *Common Stock*

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

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

## Warrants

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

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

- a) On June 30, 2021, as a result of the closing of the Business Combination, the Company assumed a total of 945,063 warrants previously issued by LACQ. The warrants provide holders the right to purchase common stock at a strike price of between \$200.00 and \$230.00 per share and expire June 30, 2026, five years following the completion of the Business Combination. A total of 500,000 of the outstanding warrants are public warrants which trade on the OTC Pink Open Market under the ticker symbol ENSCW. The remaining 445,063 warrants are private warrants with restrictions on transfer and which have the right to a cashless exercise at the option of the holder.

On August 3, 2021, the Company entered into an agreement with an existing warrant holder to reduce the exercise price of 25,000 warrants issued on June 30, 2021 from \$230.00 to \$200.00, resulting in an incremental increase in their fair value of \$56,590, recognized in general and administrative expense.

- b) On July 2, 2021, upon public listing of the Company's shares, the Company issued 55,306 warrants to purchase common stock pursuant to the share subscription facility. The warrants have a three-year life and an exercise price of \$200.20 per share. The grant date fair value of the warrants, based on the \$289.80 stock price on the date of issuance, was \$11.6 million, and was recognized in general and administrative expense due to the uncertainty of future issuance of shares under the share subscription facility.

On December 28, 2021, January 3, 2022, February 1, 2022, March 1, 2022, May 2, 2022, June 1, 2022, July 1, 2022, August 10, 2022, September 20, 2022 and September 29, 2022 the exercise price of the warrants adjusted to \$90.00 per share, \$56.60 per share, \$31.60 per share, \$19.20 per share, \$18.80 per share, \$9.20 per share, \$8.00 per share, \$7.00 per share, \$4.60 per share and \$4.00 for those conversion dates, respectively, as required by a down round adjustment feature of the warrant, due to common stock issued at a price below the then current exercise price. The difference in fair value of the existing warrant prior to the adjustment and the value of the warrant after (utilizing a "Black-Scholes model") is reflected on the consolidated statement of operations as a "deemed dividend."

- c) On September 24, 2021, the Company issued 18,058 warrants in connection with the issuance of the 2021 Notes. The warrants were immediately exercisable with an exercise price of \$152.60 (subject to downward revision protection in the event the Company makes certain issuances of common stock at prices below the conversion price) and expire on September 23, 2026. As a result of the issuance of the 2022 Notes in July of 2022, the exercise price of these warrants was adjusted down to \$15.60. The difference in fair value of the existing warrant prior to the adjustment and the value of the warrant after (utilizing a "Black-Scholes model") is reflected on the consolidated statement of operations in other income (expense).

- d) On November 5, 2021, the Company issued 36,116 warrants in connection with the issuance of the 2021 Notes. The warrants were immediately exercisable with an exercise price of \$152.60 (subject to downward revision protection in the event the Company makes certain issuances of common stock at prices below the conversion price) and expire on November 4, 2026. As a result of the issuance of the 2022 Notes in July of 2022, the exercise price of these warrants was adjusted down to \$15.60. The difference in fair value of the existing warrant prior to the adjustment and the value of the warrant after (utilizing a “Black-Scholes model”) is reflected on the consolidated statement of operations in other income (expense).
- e) On July 1, 2022, the Company issued 233,394 warrants in connection with the issuance of the 2022 Notes. The warrants were immediately exercisable with an exercise price of \$14.17 (subject to downward revision protection in the event the Company makes certain issuance of common stock at prices below the conversion price) and expire on June 29, 2027.
- f) On August 9, 2022, the Company issued 233,394 warrants in connection with the issuance of the 2022 Notes. The warrants were immediately exercisable with an exercise price of \$14.17 (subject to downward revision protection in the event the Company makes certain issuance of common stock at prices below the conversion price) and expire on August 8, 2027.

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

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

  

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

  

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



## NOTE 9 - STOCK-BASED COMPENSATION

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

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

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

In connection with the Business Combination, the Company assumed the 2021 Omnibus Incentive Plan (the “2021 Omnibus Plan”), which was approved by LACQ’s board and subsequently LACQ’s stockholders at a special stockholder meeting on June 28, 2021. The 2021 Omnibus Plan provides for the conversion with existing terms of the 221,191 options outstanding under Former Ensysce stock plans and reserves for issuance an additional 50,000 shares for future awards under the 2021 Omnibus Plan. On January 26, 2022, the 2021 Omnibus Plan was amended and restated to include an additional 150,000 shares available for future grant and to provide for future annual increases. No further awards may be made under the Former Ensysce stock plans.

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

### *Option Activity*

During the nine months ended September 30, 2022, the Company granted stock options to purchase an aggregate of 114,550 shares of common stock to employees, consultants and members of the board of directors. The options vest over periods between zero and 4 years and have an exercise price of between \$8.50 and \$125.60 per share. There were no stock option grants in 2021.

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

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

#### Option Valuation

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

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

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

The weighted-average grant date fair value of options granted during the nine months ended September 30, 2022 was \$19.24. There were no options granted during the nine months ended September 30, 2021.

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

### ***Restricted Stock Units***

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

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

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:

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

### **NOTE 10 - RELATED PARTIES**

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

### **NOTE 11 - SUBSEQUENT EVENTS**

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

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

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

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

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

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

We have incurred significant operating losses since inception. As of September 30, 2022, we had an accumulated deficit of \$105.4 million. We expect to continue to incur net losses for the foreseeable future, and we expect our clinical development expenses, and general and administrative expenses to continue to increase. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing development activities, particularly if and as we:

- continue preclinical studies and continue existing and initiate new clinical trials for 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 approvals for any product candidates that successfully complete clinical trials;
- undertake any pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval;
- expand our infrastructure and facilities to accommodate our growing employee base; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and our transition to operating as a public company.

We expect to incur additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other expenses that we did not incur as a private company.

We require substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of private and public equity offerings, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. To the extent that we raise additional capital through the sale of private or public equity or convertible debt securities, existing ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our equity holders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations or other strategic transactions with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

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

#### **Business Combination Transaction**

On January 31, 2021, LACQ executed a definitive merger agreement among it, Merger Sub and Former Ensysce, providing for, among other things, and subject to terms and conditions therein, the Business Combination. On June 30, 2021, the Business Combination was consummated. In connection with the Business Combination, the stockholders of Former Ensysce exchanged their interests for shares of the combined company's common stock at an exchange ratio of 0.06585. Immediately following the Business Combination, the stockholders of Former Ensysce owned approximately 71.8% of the outstanding common stock of the combined company. Former Ensysce's existing equity incentive plans were terminated, with awards issued under the existing equity incentive plans exchanged for awards issued under the Company's 2021 Omnibus Incentive Plan. We received net proceeds of approximately \$7.8 million at the closing of the Business Combination. We continue to operate under our management team, led by our Chief Executive Officer, Dr. Lynn Kirkpatrick. On July 2, 2021, the combined company's common stock began trading on Nasdaq under the ticker symbol "ENSC".

## Components of Ensysce's Operating Results

### *Revenue*

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

We have received funding under federal grants from the National Institutes of Health ("NIH") through the National Institute on Drug Abuse ("NIDA"). In September 2018, we were awarded a research and development grant related to the development of our MPAR<sup>TM</sup> 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<sup>TM</sup> abuse deterrent technology for Opioid Use Disorder ("OUD") (the "OUD Grant"). Grant funds are awarded annually through a Notice of Award which contains certain terms and conditions including, but not limited to, complying with the grant program legislation, regulation and policy requirements, complying with conditions on expenditures of funds with respect to other applicable statutory requirements such as the federal appropriations acts, periodic reporting requirements, and budget requirements.

### *Operating Expenses*

#### *Research and development expenses*

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

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

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

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

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

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

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

- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates.

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

#### *General and administrative expenses*

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

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

#### **Other income (expense)**

##### *Change in fair value of derivative liabilities*

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

##### *Change in fair value of convertible notes*

We elected the fair value option to account for the 2021 Notes and 2022 Notes as we believe the fair value option provides users of the financial statements with greater ability to estimate the outcome of future events as facts and circumstances change, particularly with respect to changes in the fair value of the common stock underlying the conversion option. We use a discounted cash flow model and a Monte Carlo analysis to estimate the fair value of the notes, both of which rely on unobservable Level 3 inputs. Changes in the fair value of the notes are recognized through earnings for each reporting period.



#### *Change in fair value of liability classified warrants*

The warrants issued with the 2021 Notes and 2022 Notes are liability classified due to certain cash settlement features. We use a Black-Scholes option pricing model to estimate the fair value of the warrants. Changes in the fair value of the warrants are recognized through earnings for each reporting period.

#### *Loss on debt conversions*

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

#### *Interest expense*

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

#### ***Provision for Income Taxes***

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

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or our tax returns. Deferred tax assets and liabilities are determined based on difference between the financial statement carrying amounts and tax bases of existing assets and liabilities and for loss and credit carryforwards, which are measured using the enacted tax rates and laws in effect in the years in which the differences are expected to reverse. The realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of September 30, 2022, we continue to maintain a full valuation allowance against all of our deferred tax assets based on our evaluation of all available evidence.

We file income tax returns in the United States federal tax jurisdiction and state jurisdictions and may become subject to income tax audit and adjustments by related tax authorities. Our tax return period for United States federal income taxes for the tax years since 2015 remain open to examination under the statute of limitations by the Internal Revenue Service and state jurisdictions. We record reserves for potential tax payments to various tax authorities related to uncertain tax positions, if any. The nature of uncertain tax positions is subject to significant judgment by management and subject to change, which may be substantial. These reserves are based on a determination of whether and how much a tax benefit taken by us in our tax filings or whether our position is more likely than not to be realized following the resolution of any potential contingencies related to the tax benefit. We develop our assessment of uncertain tax positions, and the associated cumulative probabilities, using internal expertise and assistance from third-party experts. As additional information becomes available, estimates are revised and refined. Differences between estimates and final settlement may occur resulting in additional tax expense. Potential interest and penalties associated with such uncertain tax positions is recorded as a component of our provision for income taxes. To date, no amounts are being presented as an uncertain tax position.

## Results of Operations

### Comparison of the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		
	2022	2021	Change
Federal grants	\$ 279,351	\$ 1,200,816	\$ (921,465)
Operating expenses:			
Research and development	4,756,096	1,714,635	3,041,461
General and administrative	1,686,580	16,372,976	(14,686,396)
Total operating expenses	6,442,676	18,087,611	(11,644,935)
Loss from operations	(6,163,325)	(16,886,795)	10,723,470
Other income (expense):			
Issuance costs for convertible notes	(1,118,721)	(500,158)	(618,563)
Loss on issuance of convertible notes	(3,609,944)	-	(3,609,944)
Change in fair value of convertible notes	3,491,513	1,071,099	2,420,414
Issuance of liability classified warrants	(3,737,371)	(1,325,804)	(2,411,567)
Change in fair value of liability classified warrants	2,683,340	405,086	2,278,254
Loss on debt conversions	(1,404,877)	-	(1,404,877)
Interest expense	(4,859)	(24,660)	19,801
Other income and expense, net	8,679	61,758	(53,079)
Total other income (expense), net	(3,692,240)	(312,679)	(3,379,561)
<b>Net loss</b>	<b>\$ (9,855,565)</b>	<b>\$ (17,199,474)</b>	<b>\$ 7,343,909</b>
Net loss attributable to noncontrolling interests	(21,492)	(35,948)	14,456
Deemed dividend related to warrants down round provision	63,539	-	63,539
<b>Net loss attributable to common stockholders</b>	<b>\$ (9,897,612)</b>	<b>\$ (17,163,526)</b>	<b>\$ 7,265,914</b>

#### Federal grant funding

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

#### Research and development expenses

Research and development expenses for the three months ended September 30, 2022 and 2021 were \$4.8 million and \$1.7 million, respectively, representing an increase of \$3.0 million. The increase was primarily the result of increased external research and development costs related to clinical and pre-clinical programs for 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 September 30, 2022 and 2021 were \$1.7 million and \$16.4 million, respectively, representing an decrease of \$14.7 million. The decrease was primarily a result of non-cash expenses incurred in the comparable prior period in connection with the valuation of issued warrants. We expect future general and administrative expenses to approximate current levels.

#### Other income and expense

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

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

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

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

*Federal grant funding*

Funding from federal grants for the nine months ended September 30, 2022 and 2021 totaled \$1.1 million and \$1.9 million, respectively, representing an decrease of \$0.8 million. Differences are due to the timing of research activities eligible for funding as well as the grant period. We expect funding from federal grants to generally increase in the future due to the timing of preclinical and clinical development activities under the grants.

*Research and development expenses*

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

*General and administrative expenses*

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

### *Other income and expense*

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

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

### **Liquidity and capital resources**

#### ***Sources of liquidity and capital***

As of September 30, 2022, we had \$4.5 million of cash and cash equivalents. Since inception, we have generated limited revenues and have incurred significant operating losses and negative cash flows from our operations, and we anticipate that we will continue to incur losses for at least the foreseeable future. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. As of September 30, 2022, we had an accumulated deficit of \$105.4 million.

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

Current remaining funding under two approved federal research grants totals \$5.8 million, covering the period through August 31, 2023. Pursuant to the terms and conditions of the two grants, we are required to submit progress reports to NIDA on an annual basis and a final research performance progress report within 120 days of the performance period end date. Additionally, the grants limit the use of funds to activities that are clearly severable and independent from activities that involve human subjects until the receipt by NIDA of (i) Institutional Review Board (“IRB”) approval, (ii) federal-wide assurance from the Office for Human Research Protections, (iii) a Data and Safety Monitoring Plan, (iv) certification that all key personnel have completed education on the protection of human subjects and (v) a Clinical Trials Dissemination Plan. We must also comply with the data sharing policies of NIDA and the NIH Public Access Policy, that require submission of final peer-reviewed journal manuscripts that arise from the use of grants to PubMed Central immediately upon acceptance for publication.

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

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

Pursuant to the GEM Agreement, we are entitled to draw down up to \$60.0 million of gross proceeds (“*Aggregate Limit*”) from GEM Global in exchange for shares of our common stock, subject to meeting the terms and conditions of the GEM Agreement. This share subscription facility is available for a period of 36 months from the closing date of the Merger. A draw down is subject to limitations on the amount that is drawn under the facility and must comply with certain conditions precedent including the listing of our shares on a principal market (which includes Nasdaq), having the necessary number of shares that are issuable pursuant to the draw down registered under an effective registration statement, and other notice and timing requirements. Upon our valid exercise of a draw down, pursuant to delivery of a notice and in accordance with other conditions, GEM Global is required to pay, in cash, a per-share amount equal to 90% of the average closing bid price of the shares of our common stock recorded by Nasdaq during the 30 consecutive trading days commencing on the first trading day that is designated on the draw down notice. In no event may our draw down requests exceed 400% (“*Draw Down Limit*”) of the average daily trading volume for the 30 trading days immediately preceding the date we deliver the draw down notice. Our ability to utilize this share subscription facility is restricted while the 2021 Notes or 2022 Notes are outstanding.

Upon the public listing of the Company’s shares following the closing of the Merger, GEM Global became entitled to a commitment fee in the form of cash or freely tradeable shares of our common stock in an amount equal to 2% of the Aggregate Limit or \$1.2 million to be paid in two tranches. The commitment fee for the first tranche, which is equal to 67% of the commitment fee, or \$800,000, was discharged with 46,062 shares of common stock transferred from related parties in July 2022. The commitment fee for the second tranche, which is equal to the remaining 33% of the commitment fee, or \$400,000, becomes payable in January 2023.

Additionally, we issued a warrant with a 36-month term at the closing of the Merger granting GEM Global the right to purchase 55,306 shares of our common stock (an amount equal to 4% of the total number of our common stock outstanding as of the closing date of the Merger (subject to adjustments described below), calculated on a fully diluted basis), at a strike price per share equal to \$200.20, which was the closing bid price for such common stock on the first day of trading on Nasdaq. The strike price was reduced to \$4.04 per share at September 30, 2022 because of a pricing adjustment per the GEM Agreement. The warrant can be exercised on a cashless basis in part or in whole at any time during the term. Any failure by us to timely transfer the shares under the warrant pursuant to GEM Global’s exercise will entitle GEM Global to compensation in addition to other remedies. The number of shares underlying the warrant as well as the strike price is subject to adjustments for recapitalizations, reorganizations, change of control, stock split, stock dividend, reverse stock splits, and issuances of additional common shares at a price per share less than the exercise price.

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

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

On September 24, 2021, we entered into a Securities Purchase Agreement for an aggregate financing of \$15.0 million with institutional investors. The Company issued to the investors (i) 2021 Notes in the aggregate principal amount of \$15.9 million for an aggregate purchase price of \$15.0 million and (ii) warrants to purchase 54,174 shares of the Company’s common stock in the aggregate at an exercise price of \$152.60 per share.

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 466,789 shares of the Company’s common stock in the aggregate at an exercise price of \$14.17 per share. The first funding of \$4.0 million occurred on July 1, 2022 and the second funding of \$4.0 million occurred on August 9, 2022.

## Cash flows

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

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

### Operating activities

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

### Investing activities

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

### Financing activities

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

### Funding requirements

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

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

- advance preclinical development of our early-stage programs and clinical trials of our product candidates;
- manufacture, or have manufactured on our behalf, preclinical and clinical drug material and develop processes for late stage 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 September 30, 2022, had an accumulated deficit of \$105.4 million. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future.

Following the completion of the Business Combination and public listing of our common stock on Nasdaq, we had access to up to \$60.0 million from a share subscription facility under the GEM agreement. The 2021 Notes and 2022 Notes limit our ability to execute certain debt and equity financings, including under the GEM Agreement, while the 2021 Notes or 2022 Notes are outstanding. Without the availability of proceeds through the share subscription facility, existing cash resources are not sufficient to allow us to fund current planned operations through the next 12 months following the filing of this 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 unaudited interim consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

### *Accrued research and development expenses*

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

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

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



### ***Stock-based compensation***

We measure all stock-based awards granted to employees, directors and non-employees based on their fair value on the date of the grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. We grant stock options and restricted stock awards that are subject to either service or performance-based vesting conditions. Compensation expense related to awards to employees and non-employees with performance-based vesting conditions is recognized based on the grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. We estimate the probability that certain performance criteria will be met and do not recognize compensation expense until it is probable that the performance-based vesting condition will be achieved.

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

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

### ***Fair value of liabilities***

We elected the fair value option to account for the 2021 Notes as we believe the fair value option provides users of the financial statements with greater ability to estimate the outcome of future events as facts and circumstances change, particularly with respect to changes in the fair value of the common stock underlying the conversion option. The Company determined that the 2022 Notes should be recorded at estimated fair value on its issuance date and adjusted to its estimated fair value as of each reporting date. We use a Monte Carlo simulation model to estimate the fair value of the 2021 Notes and 2022 Notes, which relies on unobservable Level 3 inputs. Changes in the fair value of the notes are recognized through earnings for each reporting period.

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 through earnings for each reporting period.

### **Off-balance sheet arrangements**

We do not have during the periods presented, and do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

### **Recently issued accounting pronouncements**

A description of recently issued accounting pronouncements that may potentially impact 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 September 30, 2022 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(e) and 15d-15(e)) as of September 30, 2022. 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 September 30, 2022 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, 2021 and 2020, and our unaudited interim consolidated financial statements for the three and nine months ended September 30, 2022 and 2021, 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 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 2021 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.

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

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

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

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

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

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

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

On June 17, 2022, we received written notice from Nasdaq that we were not in compliance with the Nasdaq requirement for the bid price for our common stock to be at least \$1.00 per share (the "Deficiency Letter"). We have until December 14, 2022, for the bid price for our common stock to close at \$1.00 per share or more (the "Minimum Bid Price") for a minimum of 10 consecutive business days during the compliance period ending December 14, 2022 (or such longer period of time Nasdaq may require). If compliance is not regained by December 14, 2022, Nasdaq staff will provide notice that our securities are subject to delisting. At that time, we may appeal any such delisting determination to a Nasdaq hearings panel. We actively monitor the price of the Company's common stock and are evaluating available options to resolve the deficiencies and regain compliance with the MVLS and Minimum Bid Price requirements. We effected the Reserve Split to regain compliance with the Minimum Bid Price requirement. On November 11, 2022, we received written notice from Nasdaq that we had regained compliance with the Minimum Bid Price requirement.

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

**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:

<b>Exhibit Number</b>	<b>Description</b>
10.1	<a href="#">Letter Agreement, dated September 20, 2022, by and among the Company and parties signatory thereto (incorporated by reference to Exhibit 10.6 filed with the Company’s Current Report on Form 8-K on September 20, 2022.</a>
31.1*	<a href="#">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.</a>
31.2*	<a href="#">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.</a>
32.1*	<a href="#">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.</a>
32.2*	<a href="#">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.</a>
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: November 10, 2022

*/s/ David Humphrey*

\_\_\_\_\_  
David Humphrey  
Chief Financial Officer, Secretary and Treasurer

**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: November 10, 2022

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

**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: November 10, 2022

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

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**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 September 30, 2022, 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: November 10, 2022

/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.

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**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 September 30, 2022, 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: November 10, 2022

*/s/ David Humphrey*

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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.

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