

**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, 2024

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)

7946 Ivanhoe Avenue, Suite 201  
La Jolla, California  
(Address of principal executive offices)

82-2755287  
(I.R.S. Employer  
Identification No.)

92037  
(Zip Code)

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

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

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

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

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

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

Large accelerated filer	<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 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

As of November 11, 2024, the registrant had 19,574,014 shares of common stock, \$0.0001 par value per share, outstanding.

## FORWARD-LOOKING STATEMENTS

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

- our estimates regarding expenses, revenue, capital requirements and timing and availability of and the need for additional financing will almost certainly not match actual amounts and timing;
- our ability to continue as a going concern for the next twelve months;
- the risk that our lead product candidate PF614 and PF614-MPAR may not be successful in limiting or impeding abuse, overdose, or misuse or providing additional safety upon commercialization;
- the need for substantial additional funding to complete the development and commercialization of our product candidates;
- the risk that our clinical trials may fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties;
- the risk that the potential product candidates that we develop may not progress through clinical development or receive required regulatory approvals within expected timelines or at all;
- the risk that clinical trials may not confirm any safety, potency, or other product characteristics described or assumed in this Quarterly Report on Form 10-Q;
- the risk that we will be unable to successfully market or gain market acceptance of our product candidates;
- the risk that our product candidates may not be beneficial to patients or successfully commercialized;
- the risk that we have overestimated the size of the target market, patients’ willingness to try new therapies, and the willingness of physicians to prescribe these therapies;
- effects of competition;

- the risk that third parties on which we depend for laboratory, clinical development, manufacturing, and other critical services will fail to perform satisfactorily;
- the risk that we will be unable to obtain and maintain sufficient intellectual property protection for its investigational products or will infringe the intellectual property protection of others;
- the loss of key members of our management team;
- changes in our regulatory environment;
- the ability to attract and retain key scientific, medical, commercial, or management personnel;
- changes in our industry;
- our ability to remediate any material weaknesses or establish and maintain effective internal controls over financial reporting;
- the risk that our common stock will be delisted from Nasdaq;
- The risk that we may not be able to regain or maintain compliance with applicable listing standards of Nasdaq;
- other factors disclosed in this Quarterly Report on Form 10-Q; and
- other factors beyond our control.

The forward-looking statements contained in this Quarterly Report on Form 10-Q are based on Ensysce's current expectations and beliefs concerning future developments and their potential effects on Ensysce. There can be no assurance that future developments affecting Ensysce will be those that Ensysce has anticipated. These forward-looking statements involve risks, uncertainties (some of which are beyond Ensysce's control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, and other filings with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should any of the assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Moreover, the occurrence of the events described in the "Risk Factors" in our Annual Report on Form 10-K may adversely affect Ensysce. Ensysce will not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

## GLOSSARY

### Definitions:

<b>2021 Notes</b>	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
<b>2021 Omnibus Incentive Plan</b>	Ensysce Biosciences, Inc. Amended and Restated 2021 Omnibus Incentive Plan
<b>2022 Notes</b>	The senior secured convertible promissory notes in the aggregate original principal amount of \$8.48 million, sold in two closings on June 30, 2022, and August 8, 2022, respectively, pursuant to the Securities Purchase Agreement entered into on June 30, 2022
<b>2023 Notes</b>	The senior secured convertible promissory notes in the aggregate original principal amount of \$1.8 million, sold in two closings on October 25, 2023, and November 28, 2023, respectively, pursuant to the Securities Purchase Agreement entered into on October 23, 2023
<b>2022 December Offering</b>	The Company's December 2022 registered direct offering of common stock (including pre-funded warrants in lieu thereof). The Offering closed on December 9, 2022, for aggregate consideration of \$4.1 million
<b>2023 February Offering</b>	The Company's February 2023 registered direct offering of common stock and private placement warrants for aggregate consideration of \$3.0 million
<b>2023 May Offering</b>	The Company's May 2023 registered direct offering of common stock (including pre-funded warrants in lieu thereof) for aggregate consideration of \$7.0 million
<b>2024 February Warrant Inducement</b>	The Company's February 2024 transaction including the cash exercise of certain existing warrants at a reduced price and the issuance of new warrants
<b>2024 August Warrant Inducement</b>	The Company's August 2024 transaction including the cash exercise of certain existing warrants at a reduced price and the issuance of new warrants
<b>2024 August Offering</b>	The Company's August 2024 registered direct offering of common stock, issuance of private placement warrants and the cash exercise of certain existing warrants at a reduced price and the issuance of new warrants.
<b>Abeyance shares</b>	Shares issued to certain holders and held at the Company's transfer agent to be delivered to those holders at their request. Shares held in abeyance have not been issued and are not outstanding.
<b>August Inducement Letter</b>	Inducement offer letter entered into with certain holders of existing warrants to purchase 7,203,504 shares of the Company's common stock (issued in February of 2024) to reduce the exercise price from \$1.06 per share to \$0.47 per share. The Company also agreed to amend certain existing warrants to purchase up to an aggregate of 2,000,000 shares of common stock that were previously issued in November 2023 and had an exercise price of \$1.5675 per share such that the amended warrants have a reduced exercise price of \$0.47 per share.
<b>Board</b>	Board of directors of Ensysce, or a committee thereof, as applicable
<b>Business Combination</b>	The definitive merger agreement among LACQ, Merger Sub and Former Ensysce, dated January 31, 2021, providing for, among other things, and subject to terms and conditions therein, the business combination between LACQ and Former Ensysce pursuant to the merger of Merger Sub with and into Former Ensysce, with Former Ensysce continuing as the surviving entity and as a wholly-owned subsidiary of LACQ
<b>CMOs</b>	Contract manufacturing organizations
<b>Company</b>	Ensysce Biosciences, Inc. and its consolidated subsidiaries
<b>COVID-19</b>	Novel coronavirus disease
<b>Covistat</b>	A subsidiary renamed EBIR, Inc.
<b>CROs</b>	Contract research organizations
<b>EBIR</b>	Previously known as Covistat, Inc., EBIR, Inc. is a clinical stage pharmaceutical company that is developing a compound utilized in the Company's overdose protection program for the treatment of COVID-19 and 79.2%-owned subsidiary of the Company
<b>Ensysce</b>	Ensysce Biosciences Inc.
<b>Exchange Act</b>	Securities Exchange Act of 1934, as amended
<b>FDA</b>	United States Food and Drug Administration
<b>February Inducement Letter</b>	Inducement offer letter entered into with certain holders of existing warrants to purchase 3,601,752 shares of the Company's common stock (issued on May 12, 2023) to reduce the exercise price from \$3.637 per share to \$1.31 per share.
<b>Former Ensysce</b>	Ensysce Biosciences, Inc., a Delaware corporation, prior to the consummation of the merger with and into Merger Sub
<b>GAAP</b>	Generally Accepted Accounting Principles in the United States of America
<b>GCP</b>	Good Clinical Practices

<b>Investor Notes</b>	The 2021 Notes, 2022 Notes and 2023 Notes, collectively
<b>LACQ</b>	Leisure Acquisition Corp., a Delaware Corporation
<b>LACQ Warrants</b>	Warrants that relate to the Business Combination or were issued prior to it and are exercisable for 21,993 shares of our common stock at a weighted average exercise price of \$2,725.90 per share
<b>Merger</b>	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.
<b>Merger Agreement</b>	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
<b>Merger Sub</b>	EB Merger Sub, Inc., a Delaware corporation, a wholly-owned subsidiary of LACQ prior to the consummation of the Merger
<b>MPAR Grant</b>	Research and development grant related to the development of its MPAR <sup>®</sup> overdose prevention technology awarded to the Company by NIH through NIDA in September 2018
<b>Nasdaq</b>	The Nasdaq Stock Market LLC
<b>NIDA</b>	National Institute of Drug Abuse
<b>NIH</b>	National Institutes of Health
<b>ODU Grant</b>	Research and development grant related to the development of its TAAP/MPAR <sup>®</sup> abuse deterrent technology for Opioid Use Disorder awarded to the Company by NIH/NIDA in September 2019
<b>Prior Warrants</b>	Warrants issued pursuant to the Securities Purchase Agreement. The Prior Warrants issued in (i) 2021 are exercisable for an aggregate of 4,518 shares of our common stock at an exercise price of \$3.64 per share and in (ii) 2022 are exercisable for an aggregate of 38,900 shares of our common stock at an exercise price of \$3.64 per share
<b>Public Warrants</b>	The redeemable warrants issued by us and sold as part of the units in the LACQ IPO (whether they were purchased in the LACQ IPO or thereafter in the open market). The Public Warrants are exercisable for an aggregate of approximately 41,666 shares of our common stock at an exercise price of \$2,760.00 per share
<b>Registered Direct Offering</b>	August 2024 registered direct offering of common stock (3,553,194 shares), private placement warrants (to purchase up to 7,106,388 shares) and the cash exercise of certain existing warrants (7,203,504 warrant shares) at a reduced price and the issuance of new warrants (to purchase up to 21,610,512 shares).
<b>R&amp;D</b>	Research and Development
<b>SEC</b>	U.S. Securities and Exchange Commission
<b>Securities Act</b>	Securities Act of 1933, as amended
<b>Securities Purchase Agreement</b>	The Securities Purchase Agreement, dated as of September 24, 2021, June 30, 2022, October 23, 2023, or August 28, 2024, as the context dictates, by and between Ensysce and the institutional investors party thereto
<b>SPA</b>	A Securities Purchase Agreement, dated as of September 24, 2021, June 30, 2022, October 23, 2023, or August 28, 2024 as the context dictates, by and between Ensysce and the institutional investors party thereto
<b>TAAP</b>	Trypsin Activated Abuse Protection

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

ENSYSCE BIOSCIENCES, INC.  
CONSOLIDATED BALANCE SHEETS  
(Unaudited)

	September 30, 2024	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 4,153,592	\$ 1,123,604
Unbilled receivable	1,782,805	97,561
Prepaid expenses and other current assets	3,154,110	1,067,703
Total current assets	9,090,507	2,288,868
Other assets	294,217	419,217
<b>Total assets</b>	<b>\$ 9,384,724</b>	<b>\$ 2,708,085</b>
<b>Liabilities and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,967,573	\$ 1,936,007
Accrued expenses and other liabilities	447,035	542,260
Notes payable and accrued interest	387,176	854,697
Total current liabilities	2,801,784	3,332,964
Long-term liabilities:		
Liability classified warrants	3,213	26,388
Total long-term liabilities	3,213	26,388
<b>Total liabilities</b>	<b>\$ 2,804,997</b>	<b>\$ 3,359,352</b>
Commitments and contingencies (Note 6)		
<b>Stockholders' equity (deficit)</b>		
Preferred stock, \$0.0001 par value, 1,500,000 shares authorized, no shares issued and outstanding at September 30, 2024 (unaudited) and December 31, 2023	\$ -	\$ -
Common stock, \$0.0001 par value, 250,000,000 shares authorized at September 30, 2024 (unaudited) and December 31, 2023; 13,870,591 and 3,146,157 shares issued at September 30, 2024 (unaudited) and December 31, 2023, respectively; 13,870,510 and 3,146,076 shares outstanding at September 30, 2024 (unaudited) and December 31, 2023, respectively	1,387	315
Additional paid-in capital	132,886,700	121,233,901
Accumulated deficit	(125,979,877)	(121,557,074)
Total Ensysce Biosciences, Inc. stockholders' equity (deficit)	6,908,210	(322,858)
Noncontrolling interests in stockholders' deficit	(328,483)	(328,409)
<b>Total stockholders' equity (deficit)</b>	<b>6,579,727</b>	<b>(651,267)</b>
<b>Total liabilities and stockholders' equity (deficit)</b>	<b>\$ 9,384,724</b>	<b>\$ 2,708,085</b>

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
<b>Federal grants</b>	\$ 3,418,853	\$ 435,380	\$ 3,906,372	\$ 1,715,488
<b>Operating expenses:</b>				
Research and development	1,690,674	1,914,970	3,416,807	5,354,713
General and administrative	1,083,433	1,227,724	3,643,223	3,923,277
Total operating expenses	<u>2,774,107</u>	<u>3,142,694</u>	<u>7,060,030</u>	<u>9,277,990</u>
<b>Income (loss) from operations</b>	644,746	(2,707,314)	(3,153,658)	(7,562,502)
<b>Other income (expense):</b>				
Change in fair value of convertible notes	-	-	-	146,479
Change in fair value of liability classified warrants	6,403	17,223	23,175	279,873
Interest expense, net	(4,063)	(7,649)	(1,279,691)	(9,146)
Other income (expense), net	14,683	6,934	(12,413)	23,382
Total other income (expense), net	<u>17,023</u>	<u>16,508</u>	<u>(1,268,929)</u>	<u>440,588</u>
<b>Net income (loss)</b>	\$ 661,769	\$ (2,690,806)	\$ (4,422,587)	\$ (7,121,914)
Net loss attributable to noncontrolling interests	-	(1,235)	(74)	(12,236)
Deemed dividend related to warrants down round provision	-	-	290	12,038
<b>Net income (loss) attributable to common stockholders</b>	<u>\$ 661,769</u>	<u>\$ (2,689,571)</u>	<u>\$ (4,422,803)</u>	<u>\$ (7,121,716)</u>
<b>Net income (loss) per basic and diluted share:</b>				
Net income (loss) per share attributable to common stockholders, basic and diluted	<u>\$ 0.07</u>	<u>\$ (0.87)</u>	<u>\$ (0.57)</u>	<u>\$ (3.32)</u>
Weighted average common shares outstanding, basic and diluted	9,890,390	3,085,873	7,782,540	2,145,505

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, 2023</b>	2,669,792	\$ 267	\$ 119,481,957	\$ (115,363,208)	\$ (326,209)	\$ 3,792,807
Settlement of restricted stock units	314	-	-	-	-	-
Issuance of common stock upon exercise of warrants	193,898	20	(20)	-	-	-
Stock-based compensation	-	-	55,674	-	-	55,674
Net loss	-	-	-	(2,689,571)	(1,235)	(2,690,806)
<b>Balance on September 30, 2023</b>	<b>2,864,004</b>	<b>\$ 287</b>	<b>\$ 119,537,611</b>	<b>\$ (118,052,779)</b>	<b>\$ (327,444)</b>	<b>\$ 1,157,675</b>
<b>Balance on June 30, 2024</b>	<b>8,151,172</b>	<b>\$ 815</b>	<b>\$ 128,448,699</b>	<b>\$ (126,641,646)</b>	<b>\$ (328,483)</b>	<b>\$ 1,479,385</b>
Public offering	3,553,194	355	1,669,646	-	-	1,670,001
Issuance of common stock upon warrant inducement	2,166,144	217	3,385,430	-	-	3,385,647
Transaction costs associated with public offering and warrant inducement	-	-	(637,894)	-	-	(637,894)
Stock-based compensation	-	-	20,819	-	-	20,819
Net income	-	-	-	661,769	-	661,769
<b>Balance on September 30, 2024</b>	<b>13,870,510</b>	<b>\$ 1,387</b>	<b>\$ 132,886,700</b>	<b>\$ (125,979,877)</b>	<b>\$ (328,483)</b>	<b>\$ 6,579,727</b>
<b>Balance on December 31, 2022</b>	534,490	\$ 53	\$ 107,216,566	\$ (110,931,063)	\$ (315,208)	\$ (4,029,652)
Settlement of restricted stock units	938	-	-	-	-	-
Settlement of commitment fee	44,444	4	399,996	-	-	400,000
Conversion of convertible notes	408,580	41	3,056,851	-	-	3,056,892
Public offerings, net	1,381,619	139	9,049,865	-	-	9,050,004
Transaction costs associated with public offerings	-	-	(447,879)	-	-	(447,879)
Issuance of common stock upon exercise of warrants	494,795	50	(50)	-	-	-
Stock-based compensation	-	-	250,224	-	-	250,224
Reverse split fractional shares	(862)	-	-	-	-	-
Deemed dividend related to warrants down round provision	-	-	12,038	(12,038)	-	-
Net loss	-	-	-	(7,109,678)	(12,236)	(7,121,914)
<b>Balance on September 30, 2023</b>	<b>2,864,004</b>	<b>\$ 287</b>	<b>\$ 119,537,611</b>	<b>\$ (118,052,779)</b>	<b>\$ (327,444)</b>	<b>\$ 1,157,675</b>
<b>Balance on December 31, 2023</b>	3,146,076	\$ 315	\$ 121,233,901	\$ (121,557,074)	\$ (328,409)	\$ (651,267)
Settlement of restricted stock units	63	-	-	-	-	-
Conversion of convertible notes	745,521	75	1,168,525	-	-	1,168,600
Public offering	3,553,194	355	1,669,646	-	-	1,670,001
Issuance of common stock upon exercise of warrants	1,323,904	132	2,075,087	-	-	2,075,219
Issuance of common stock upon warrant inducements	5,101,752	510	8,103,433	-	-	8,103,943
Transaction costs associated with public offering and warrant inducements	-	-	(1,444,756)	-	-	(1,444,756)
Stock-based compensation	-	-	80,574	-	-	80,574
Deemed dividend related to warrants down round provision	-	-	290	(290)	-	-
Net loss	-	-	-	(4,422,513)	(74)	(4,422,587)
<b>Balance on September 30, 2024</b>	<b>13,870,510</b>	<b>\$ 1,387</b>	<b>\$ 132,886,700</b>	<b>\$ (125,979,877)</b>	<b>\$ (328,483)</b>	<b>\$ 6,579,727</b>

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

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

	Nine Months Ended September 30,	
	2024	2023
<b>Cash flows from operating activities:</b>		
Net loss	\$ (4,422,587)	\$ (7,121,914)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accrued interest and interest expense related to note conversions	33,175	9,146
Amortization of original issue discount and debt issuance costs	1,197,200	-
Change in fair value of liability classified warrants	(23,175)	(279,873)
Change in fair value of convertible notes	-	(146,479)
Stock-based compensation	80,574	250,224
Lease cost	-	(135)
Changes in operating assets and liabilities:		
Unbilled receivable	(1,685,244)	169,083
Prepaid expenses and other assets	(1,729,252)	1,235,252
Accounts payable	(57,666)	(2,027,375)
Accrued expenses and other liabilities	(131,635)	(1,066,036)
Net cash used in operating activities	(6,738,610)	(8,978,107)
<b>Cash flows from financing activities:</b>		
Proceeds public offerings, net	1,670,001	9,050,004
Proceeds from warrant exercises	2,075,219	-
Proceeds from warrant inducement, net of issuance costs	8,103,943	-
Transaction costs associated with public offerings	-	(447,879)
Transaction costs associated with public offering and warrant inducements	(1,319,115)	-
Repayments of convertible notes	(485,190)	(1,000,208)
Repayment of financed insurance premiums	(276,260)	(307,131)
Net cash provided by financing activities	9,768,598	7,294,786
Increase (decrease) in cash and cash equivalents	3,029,988	(1,683,321)
<b>Cash and cash equivalents beginning of period</b>	<b>1,123,604</b>	<b>3,147,702</b>
<b>Cash and cash equivalents end of period</b>	<b>\$ 4,153,592</b>	<b>\$ 1,464,381</b>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Incremental fair value of August 2024 Warrant Inducement	\$ 10,210,616	\$ -
Incremental fair value of February 2024 Warrant Inducement	\$ 5,167,372	\$ -
Conversions of convertible notes into common stock	\$ 1,168,600	\$ 3,056,892
Proceeds from financed insurance premiums, net	\$ 232,155	\$ 445,737
Transaction costs from warrant inducement and public offering included in accounts payable	\$ 125,641	\$ -
Deemed dividend related to warrants down round provision	\$ 290	\$ 12,038
Settlement of commitment fee in shares	\$ -	\$ 400,000

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

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

**NOTE 1 – ORGANIZATION AND PRINCIPAL ACTIVITIES**

Ensysce Biosciences, Inc. (“Ensysce”), along with its 79.2%-owned subsidiary, EBIR, Inc. (“EBIR”, formerly known as Covistat, Inc.) and its wholly-owned subsidiaries EBI Operating, Inc. and EBI OpCo, Inc. (collectively, the “Company”), is a clinical-stage pharmaceutical company using its proprietary technology platforms to develop safer prescription drugs. The primary focus of the Company is developing abuse- and overdose-resistant pain technology, with a lead product candidate in the abuse-resistant, TAAP (Trypsin-Activated Abuse Protection) opioid, PF614. In addition, the Company is developing its MPAR<sup>®</sup> (Multi-Pill Abuse Resistance) technology for overdose protection, which is being applied to the PF614 program with a second product candidate, PF614-MPAR. The Company is also applying its TAAP and MPAR<sup>®</sup> technology to a methadone prodrug for use in the treatment of Opioid Use Disorder.

In 2020, the Company commenced an initiative to develop a therapeutic for the treatment of certain coronavirus infections through the formation of a separate entity, EBIR, a Delaware corporation. Pursuant to the certificate of incorporation, EBIR was authorized to issue 1,000,000 shares of common stock, \$0.001 par value per share, and 100,000 shares of preferred stock, \$0.001 par value per share. Ensysce is a 79.2% stockholder in EBIR, with 9.9% and 10.9% of the shares held by a certain key person of the Company and two unrelated parties, respectively. The non-Ensysce owned shares and the activity are reflected on the financial statements as Noncontrolling interests.

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

**NOTE 2 - BASIS OF PRESENTATION**

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

In the opinion of management, all adjustments considered necessary for a fair presentation have been included in the consolidated financial statements. Operating results for the nine months ended September 30, 2024, are not necessarily indicative of the results that may be expected for the year ending December 31, 2024. 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, 2023, which may be found in the Company’s Form 10-K filed with the SEC on March 15, 2024.

***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. There is no assurance that profitable operations will ever be achieved, and, if achieved, will 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.

While the Company believes in the viability of its strategy to ultimately realize revenues and in its ability to raise additional funds, management cannot be certain that additional funding will be available on acceptable terms, or at all. The Company's ability to continue as a going concern is dependent upon its ability to obtain adequate financing and achieve profitable operations. As a result, these plans do not alleviate substantial doubt about the Company's ability to continue as a going concern for a period of 12 months following the date these consolidated financial statements were issued.

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

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

#### ***Use of estimates and assumptions***

Preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and disclosed in the accompanying notes. Actual results may differ from those estimates and such differences may be material to the consolidated financial statements. The more significant estimates and assumptions by management include, but are not limited to, the expense recognition for certain accrued research and development services.

#### ***Cash and cash equivalents***

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

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

Cash and cash equivalents are financial instruments that are potentially subject to concentrations of credit risk. The Company's cash and cash equivalents are deposited in accounts at large financial institutions and amounts currently exceed federally insured limits. The Company has no financial instruments with off-balance sheet risk of loss. Additionally, the Company had concentration in accounts payable, as one and two research and development vendors, respectively, made up greater than 10% individually, and 72% and 38% in aggregate, of the outstanding accounts payable balance as of September 30, 2024, and December 31, 2023, respectively.

#### ***Property and equipment***

Property and equipment are fully depreciated and as such there is no depreciation expense recognized in the periods presented.

#### ***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, 2024, and December 31, 2023, 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.

## Warrants

The Company issued liability-classified warrants in connection with the issuance of the 2021 Notes and 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 by using assumptions within the model for the expected volatility, expected term, risk-free interest rate and dividend yield. Changes in the fair value of the warrants are recognized in other income (expense) for each reporting period. Refer to Note 8 for details of the warrants.

The following tables present liabilities measured and recorded at fair value on the Company’s consolidated balance sheets as of September 30, 2024, and December 31, 2023.

	<b>September 30, 2024</b>			
	<b>Total</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
Liability classified warrants	\$ 3,213	\$ -	\$ -	\$ 3,213
Total	<u>\$ 3,213</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 3,213</u>

  

	<b>December 31, 2023</b>			
	<b>Total</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
Liability classified warrants	26,388	-	-	26,388
Total	<u>\$ 26,388</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 26,388</u>

The following table summarizes the change in fair value of the Company’s Level 3 liabilities for the nine months ended September 30, 2024 (no level 3 assets as of the nine months ended September 30, 2024):

	<b>Liability classified warrants</b>
Fair value, December 31, 2023	\$ 26,388
Change in fair value	(23,175)
Fair value, September 30, 2024	<u>\$ 3,213</u>

## Federal Grants

In September 2018, the National Institutes of Health (“NIH”) through the National Institute on Drug Abuse (“NIDA”) awarded the Company a research and development grant related to the development of its MPAR<sup>®</sup> overdose prevention technology (the “MPAR Grant”). The initial grant was extended several times and cumulative funding under this grant of approximately \$10.7 million was completed in December 2023. A new multi-year MPAR Grant was awarded by NIH through NIDA in August 2024, providing funding of \$14 million through May 2027.

In September 2019, the NIH/NIDA awarded the Company a second research and development grant related to the development of its TAAP/MPAR abuse deterrent technology for Opioid Use Disorder (the “OUD Grant”). The total approved budget was approximately \$5.4 million, and the grant period ended August 31, 2024.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
MPAR	\$ 1,782,805	\$ 119,942	\$ 1,782,805	\$ 1,038,484
TAAP/OUD	1,636,048	315,438	2,123,567	677,004
<b>Total</b>	<b>\$ 3,418,853</b>	<b>\$ 435,380</b>	<b>\$ 3,906,372</b>	<b>\$ 1,715,488</b>

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 in a timely manner, no valuation allowances are recorded.

***Research and development costs***

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

***General and administrative expenses***

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

***Stock-based compensation***

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

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model. The assumptions used in calculating the fair value of stock-based awards represent management’s best estimates and involve inherent uncertainties and the application of management’s judgment. 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.

### ***Net income (loss) 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. Basic shares outstanding include the weighted average effect of the Company’s outstanding pre-funded warrants and abeyance shares, which require no consideration for the delivery of shares of common stock. Diluted net income (loss) per share is calculated by adjusting basic shares outstanding for the dilutive effect of common share equivalents outstanding for the period.

The following weighted average shares have been excluded from the calculations of diluted weighted average common shares outstanding because they would have been anti-dilutive (the Company has utilized the principal balance outstanding and the end of period conversion price for the Convertible Notes for the purposes of the weighted average share calculation below):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>	<b>2024</b>	<b>2023</b>
Stock options	580,414	26,354	580,414	26,354
RSUs	-	63	-	63
Warrants	18,830,377	4,711,236	13,194,861	2,876,380
Convertible notes	137,799	-	137,799	-
<b>Total</b>	<b>19,548,590</b>	<b>4,737,653</b>	<b>13,913,074</b>	<b>2,902,797</b>

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

In November 2023, the FASB issued ASU 2023-07, “Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures”, which sets forth improvements to the current segment disclosure requirements in accordance with Topic 280 “Segment Reporting,” including clarifying that entities with a single reportable segment are subject to both new and existing segment reporting requirements. ASU 2023-07 will be effective retrospectively for fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024. Adoption of this ASU is currently being evaluated by the Company.

In December 2023, the FASB issued ASU No. 2023-09, “Income Taxes (Topic 740): Improvements to Income Tax Disclosures.” ASU 2023-09 requires disaggregated information about a reporting entity’s effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

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

Prepaid expenses and other current assets consisted of the following:

	September 30, 2024	December 31, 2023
Prepaid research and development	\$ 2,652,845	\$ 535,474
Prepaid insurance	378,360	441,871
Other prepaid expenses	104,905	72,358
Other current assets	18,000	18,000
Total prepaid expenses and other current assets	<u>\$ 3,154,110</u>	<u>\$ 1,067,703</u>

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

Accrued expenses and other liabilities consisted of the following:

	September 30, 2024	December 31, 2023
Accrued research and development	\$ 214,251	\$ 329,228
Professional fees	95,730	110,202
Other accrued liabilities	137,054	102,830
Total accrued expenses and other liabilities	<u>\$ 447,035</u>	<u>\$ 542,260</u>

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

As of September 30, 2024, the Company's commitments included approximately \$13.3 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, 2024, and December 31, 2023, there were no pending legal proceedings against the Company that are expected to have a material adverse effect on cash flows, financial condition or results of operations. From time to time, the Company could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. Periodically, the Company reviews the status of significant matters, if any exist, and assesses its potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount can be estimated, the Company accrues a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict. Because of such uncertainties, accruals are based on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation.

*Lease*

The Company's current lease agreement (as amended) has a term that extends through October 31, 2025, with no contracted option to renew. As of September 30, 2024, the future lease payments totaled \$38,294. The Company recognized total rent expense of \$8,747 and \$26,242 in the three and nine months ended September 30, 2024, and \$8,375 and \$25,124 in the three and nine months ended September 30, 2023.

**NOTE 7 – NOTES PAYABLE**

The following table provides a summary of the Company's outstanding debt as of September 30, 2024:

	<b>Principal balance</b>	<b>Accrued interest</b>	<b>Net debt balance</b>
2023 Notes	\$ 216,000	\$ 6,308	\$ 222,308
Financed insurance	164,868	-	164,868
<b>Total</b>	<b>\$ 380,868</b>	<b>\$ 6,308</b>	<b>\$ 387,176</b>

The following table provides a summary of the Company's outstanding debt as of December 31, 2023:

	<b>December 31, 2023</b>			
	<b>Principal balance</b>	<b>Accrued interest</b>	<b>Unamortized Debt Discount and Issuance Costs</b>	<b>Net debt balance</b>
2023 Notes	\$ 1,836,000	\$ 13,078	\$ (1,197,200)	\$ 651,878
Financed insurance	197,249	5,570	-	202,819
<b>Total</b>	<b>\$ 2,033,249</b>	<b>\$ 18,648</b>	<b>\$ (1,197,200)</b>	<b>\$ 854,697</b>

### **Interest Expense**

The interest expense recognized for notes payable was as follows:

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2024</b>	<b>2023</b>	<b>2024</b>	<b>2023</b>
Stated interest accrual	\$ 4,063	\$ 7,649	\$ 6,155	\$ 9,146
2023 Notes	-	-	1,273,536	-
Total	<u>\$ 4,063</u>	<u>\$ 7,649</u>	<u>\$ 1,279,691</u>	<u>\$ 9,146</u>

### **2023 Notes**

On October 23, 2023, the Company entered into a Securities Purchase Agreement (“SPA”) for an aggregate financing of \$1.8 million with investors, including \$0.2 million with a board member. At the first closing under the SPA, which occurred on October 25, 2023, the Company issued to the investors (i) senior secured convertible promissory notes in the aggregate principal amount of \$612,000 for an aggregate purchase price of \$566,667 and (ii) warrants to purchase 1,255,697 shares of the Company’s common stock, par value \$0.0001 per share in the aggregate. At the second closing under the SPA, which occurred on November 29, 2023, the Company issued to the investors referenced above, (i) additional notes in the aggregate principal amount of \$1,224,000 for an aggregate purchase price of \$1,133,333 and (ii) additional warrants to purchase 2,511,394 shares of the common stock in the aggregate.

The Company reflected the outstanding principal amount, the remaining unamortized discount (both original issue discount and the relative fair value discount associated with the warrants discussed below) and the remaining debt issuance costs as a net amount on the face of the balance sheet. The amortization of the original debt discount (approximately \$0.1 million) and issuance costs (approximately \$0.3 million) were recorded as interest expense within the consolidated statements of operations. As of September 30, 2024, the original debt discount and issuance costs were fully amortized to interest expense.

The warrants have an exercise price of \$1.5675, the same as the conversion price, and are exercisable for five years following the issuance date. The warrants were equity classified as they are indexed to the Company’s stock and only settleable in shares. The warrants were initially measured at fair value using a Black-Scholes valuation model and were allocated along with the 2023 Notes using the relative fair value method. The initial fair value of \$1.1 million allocated to the warrants was considered a debt discount and was amortized to interest expense over the remaining term of the notes. As of September 30, 2024, the discount associated with the warrants was fully amortized to interest expense.

During 2024, the Company converted 745,521 shares of common stock with a conversion value of \$1.2 million related to the 2023 Notes. In addition, in connection with the SPA, the Company incurred a \$1.0 million waiver fee as a result of the 2024 February Warrant Inducement (see Note 8) to pay down \$0.5 million of the 2023 Notes and incurred \$0.5 million in transaction costs recorded as such in the consolidated statement of stockholders' equity. As of September 30, 2024, the remaining amount of the 2023 Notes relates to senior secured convertible promissory notes held by a Company board member (see Note 10).

#### *Financed insurance premiums*

In June 2024, the Company renewed and financed its directors' and officers' liability insurance in the amount of \$0.2 million. Monthly payments are scheduled from July 2024 through March 2025.

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

The Company's current Certificate of Incorporation authorizes 250,000,000 shares of common stock and 1,500,000 shares of preferred stock, both with par value equal to \$0.0001. As of September 30, 2024, and December 31, 2023, there were no shares of preferred stock issued and outstanding.

#### *2024 February Warrant Inducement*

In February 2024, the Company executed an Inducement Letter with certain holders of existing warrants to purchase up to an aggregate of 3,601,752 shares of the Company's common stock issued to the holders in connection with the 2023 May Offering. Pursuant to the Inducement Letter, the holders agreed to exercise for cash their existing warrants to purchase an aggregate of 3,601,752 shares of Common Stock at a reduced exercise price of \$1.31 per share in consideration of the Company's agreement to issue new unregistered Series A Warrants (the "Series A Warrants") to purchase up to 3,601,752 shares of Common Stock and new unregistered Series B Warrants (the "Series B Warrants") to purchase up to 3,601,752 shares of Common Stock (collectively, the "New Warrant Shares"). The Series A Warrants have an exercise price of \$1.06 per share and have a term equal to eighteen months from the date of issuance. The Series B Warrants have an exercise price of \$1.06 per share and will expire on May 12, 2028. The gross proceeds to the Company from the exercise of the warrants were approximately \$4.7 million, prior to deducting placement agent fees and estimated offering expenses. As the existing warrants and the new warrants were equity classified before and after the exchange, and as the exchange is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately \$5.2 million as an equity issuance cost.

In connection with the execution of the Inducement Letter, the Company executed a waiver related to the 2023 Notes' SPA it had entered as of October 23, 2023. The SPA contained restrictions on the Company's ability to undertake certain transactions, which included the execution of the Inducement Letter. The Waiver permitted the Company to execute the Inducement Letter but required repayment of the certain investor held notes issued under the SPA with a premium following closing of the transaction. Refer to Note 7 for the details of the waiver fee and the application of the amounts to the outstanding 2023 Notes and as a transaction cost of the warrant inducement.

The Company utilized an exclusive placement agent for the 2024 February Warrant Inducement and incurred approximately \$0.3 million in legal fees and other closing costs. Additionally, the Company issued to the placement agent as compensation unregistered warrants to purchase up to 252,123 shares of Common Stock, equal to 7.0% of the aggregate number of shares of Common Stock (or warrants) placed in the transaction. The placement agent warrants expire on May 12, 2028, and have an exercise price of \$1.6375 per share of Common Stock (equal to 125% of the reduced exercise price per Existing Warrant).

#### *2024 Registered Direct Offering and 2024 August Warrant Inducement*

In August 2024, the Company entered into a definitive Securities Purchase Agreement with certain institutional investors, pursuant to which the Company agreed to issue and sell in a registered direct offering, (i) an aggregate of 2,490,798 shares of common stock, par value \$0.0001 per share at an offering price of \$0.47 per share, (ii) pre-funded warrants to purchase up to 1,062,396 shares of common stock, at a price per pre-funded warrant equal to \$0.4699, the price per share less \$0.0001, for gross proceeds of approximately \$1.67 million before the deduction of placement agent fees and offering expenses. The pre-funded warrants were subsequently exercised in full and were not outstanding as of September 30, 2024.

The Company also entered into the August Inducement Letter with certain warrant holders for the exercise of certain outstanding warrants to purchase up to an aggregate of 7,203,504 shares of common stock of the Company originally issued in February 2024, having an exercise price of \$1.06 per share, at a reduced exercise price of \$0.47 per share. The Company also agreed to amend certain existing warrants to purchase up to an aggregate of 2,000,000 shares of common stock that were previously issued in November 2023 and have an exercise price of \$1.5675 per share such that the amended warrants will have a reduced exercise price of \$0.47 per share effective upon the closing of the offering and will be exercisable from the date on which stockholder approval is received with respect to the issuance of the shares of common stock issuable upon exercise of such warrants. As the existing November 2023 and February 2024 warrants and their related newly issued warrants upon inducement were equity classified before and after the exchange, and as the exchange is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately \$10.2 million as an equity issuance cost.

In a concurrent private placement, pursuant to the terms of the August Inducement Letter and Securities Purchase Agreement, the Company utilized an exclusive placement agent for the 2024 Registered Direct Offering and 2024 August Warrant Inducement and incurred approximately \$0.6 million in legal fees and other closing costs. Additionally, the Company issued to the placement agent as compensation unregistered warrants to purchase up to 752,969 shares of Common Stock. The placement agent warrants expire on August 28, 2029, and have an exercise price of \$0.5875 per share of Common Stock. The warrants will become exercisable upon stockholder approval and contain customary anti-dilution adjustments to the exercise price, including for share splits, share dividends, rights offering and pro rata distributions.

### *Abeyance Shares*

Related to the 2024 February Warrant Inducement, a holder left 1,488,144 shares in abeyance at the Company's transfer agent to be delivered to the holder at their request. During the quarter ended September 30, 2024, all remaining shares held in abeyance were delivered to the holder.

Related to the 2024 August Warrant Inducement, four holders left 7,203,504 shares in abeyance at the Company's transfer agent to be delivered to the holder at their request. During the quarter ended September 30, 2024, 1,500,000 shares held in abeyance were delivered to the holders. Accordingly, as of September 30, 2024, 5,703,504 shares were held in abeyance, had not been issued and were not outstanding. Subsequent to September 30, 2024, the remaining shares were delivered to the holders.

### *Warrants*

The following table provides a summary of outstanding warrants to purchase shares of common stock as of September 30, 2024:

Reference	Shares Underlying Outstanding Warrants	Exercise Price	Description	Classification
(a)	29,469,869	\$ 0.47 - \$0.5875	August 2024 Warrants	Equity
(b)	252,123	\$ 1.64	February 2024 Warrants	Equity
(c)	2,443,187	\$ 0.47 - \$1.5675	2023 Notes Warrants	Equity
(d)	1,101,582	\$ 3.64 - \$2,760	Other Warrants	Equity & Liability
	<u>33,266,761</u>			

- (a) On August 29, 2024, in connection with the 2024 Registered Direct Offering and 2024 August Warrant Inducement, the Company issued equity classified warrants to purchase 29,469,869 shares to certain institutional investors and the placement agent. The warrants were issued in connection with the 2024 Registered Direct Offering and the 2024 August Warrant Inducement. The 28,716,900 investor warrants have an exercise price of \$0.47 per share, and are exercisable from the date on which stockholder approval is received. One half of the warrants will expire eighteen months after they are exercisable, and the other half will expire five years after they are exercisable. The 752,969 placement agent warrants have an exercise price of \$0.5875 per share, are exercisable upon stockholder approval and expire August 28, 2029.
- (b) On February 12, 2024, the Company issued 7,455,627 equity classified warrants (Series A Warrants, Series B Warrants and placement agent warrants) in connection with the Inducement Letter for the 2024 February warrant inducement and related warrant restructuring. The Series A and Series B Warrants were immediately exercisable with an exercise price of \$1.06 per share and expire on August 14, 2025 and May 12, 2028, respectively. The placement agent warrants were immediately exercisable with an exercise price of \$1.6375 per share and expire on May 12, 2028. In connection with the 2024 August Warrant Inducement, 7,203,504 warrants were exercised. As of September 30, 2024, the placement agents remain outstanding.
- (c) On October 25, 2023, and November 28, 2023, the Company issued warrants to purchase 1,255,697 shares and 2,511,394 shares, respectively. The warrants were immediately exercisable with an exercise price of \$1.5675 per share and expire on October 25, 2028, and November 28, 2028, respectively. In January 2024, a holder of the warrants exercised 1,323,904 warrants at an exercise price of \$1.5675 per share. In August 2024, an inducement letter was issued to a holder of 2,000,000 warrants to reduce the exercise price from \$1.5675 to \$0.47 per share, subject to the receipt of stockholder approval.
- (d) At various dates from the Closing of the Business Combination through September 30, 2023, the Company assumed or issued a total of 1,101,582 warrants to provide holders the right to purchase common stock at exercise prices ranging from \$3.64 - \$2,760 per share. A total of 41,666 of the outstanding warrants are public warrants which trade on the OTC Pink Open Market under the ticker symbol ENSCW. A total of 43,418 outstanding warrants (issued in connection with the 2021 and 2022 Notes) are liability-classified due to certain cash settlement features embedded within the warrant agreements. The remaining warrants are equity classified. The warrants expire beginning June 30, 2026, through August 7, 2028.

## NOTE 9 - STOCK-BASED COMPENSATION

In connection with the Business Combination, the Company assumed the 2021 Omnibus Incentive Plan. In February 2024, the Company's Board approved an annual increase of 157,304 shares available for future grant under the 2021 Omnibus Plan.

The Company recognized stock-based compensation expense within general and administrative expense of \$14,497 and \$56,643 for the three and nine months ended September 30, 2024, and \$41,336 and \$198,000 for the three and nine months ended September 30, 2023. The Company recognized stock-based compensation expense within research and development expense of \$6,322 and \$23,931 for the three and nine months ended September 30, 2024, and \$14,338 and \$52,224 for the three and nine months ended September 30, 2023.

### *Option Activity*

There were no stock options granted during the nine months ended September 30, 2024.

The following table summarizes the Company's stock option activity during the nine months ended September 30, 2024:

	Options	Weighted average		Intrinsic value
		Exercise price	Remaining contractual life	
Outstanding at December 31, 2023	581,314	\$ 33.15	9.57	\$ -
Granted	-	-	-	-
Exercised	-	-	-	-
Expired / Forfeited	-	-	-	-
Outstanding at September 30, 2024	581,314	33.15	8.83	-
Exercisable at September 30, 2024	580,414	32.48	-	-
Vested and expected to vest	581,314	33.15	8.83	-

### 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 during the nine months ended September 30, 2024 and 2023):

- *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.

As of September 30, 2024, the Company had an aggregate of \$39,273 of unrecognized share-based compensation cost, which is expected to be recognized over the weighted average period of 0.83 years.

### Shares Reserved for Future Issuance

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

	<u>September 30, 2024</u>
Awards outstanding under the 2021 Omnibus Incentive Plan	581,314
Awards available for future grant under 2021 Omnibus Incentive Plan	159,416
Warrants outstanding	33,266,761
Total shares of common stock reserved for future issuance	<u>34,007,491</u>

### NOTE 10 - RELATED PARTIES

As of September 30, 2024, the Company held a \$0.2 million senior secured convertible promissory note plus accrued interest and 0.4 million warrants exercisable for common stock at \$1.5675 per share issued to a board member in connection to the issuance of the 2023 Notes. On April 25, 2024, the Company and the board member entered into a forbearance agreement that will expire on April 25, 2025. Upon termination of the forbearance period, the Company will owe the remaining outstanding principal balance together with unpaid interest. The Company may pay the notes in full at any time prior to the conclusion of the forbearance period.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

*The following discussion and analysis provide information which our management believes is relevant to an assessment and understanding of our consolidated results of operations and financial condition. You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and notes thereto included elsewhere in this report. In addition to historical financial information, this discussion contains forward-looking statements based upon our current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section within Part II-Other Information - titled "Item 1A. Risk Factors."*

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

### Overview

Ensysce is a clinical stage pharmaceutical company developing innovative solutions for severe pain relief while reducing the potential for opioid abuse and overdose. 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 effect of the medication more quickly than by swallowing. Our MPAR® technology adds a layer of overdose protection to each TAAP product.

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

Our lead product candidate, PF614, is ready for Phase 3 clinical development, PF614-MPAR is in Phase 1b clinical development and nafamostat has completed Phase 1 clinical development. Our other product candidates and our research initiatives are in preclinical or earlier stages of development. Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. We have not yet successfully completed any pivotal clinical trials, nor have we obtained any regulatory approvals, manufactured a commercial-scale drug, or conducted sales and marketing activities.

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

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

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

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

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

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

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

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

#### *2024 February Warrant Inducement*

In February 2024, the Company entered into an Inducement Letter with certain holders of existing warrants to purchase up to an aggregate of 3,601,752 shares of the Company's common stock issued to the holders in connection with the 2023 May Offering. Pursuant to the Inducement Letter, the holders agreed to exercise for cash their existing warrants to purchase an aggregate of 3,601,752 shares of Common Stock at a reduced exercise price of \$1.31 per share in consideration of the Company's agreement to issue new unregistered Series A Warrants to purchase up to 3,601,752 shares of Common Stock and new unregistered Series B Warrants to purchase up to 3,601,752 shares of Common Stock. The Series A Warrants have an exercise price of \$1.06 per share and have a term equal to eighteen months from the date of issuance. The Series B Warrants have an exercise price of \$1.06 per share and will expire on May 12, 2028. The gross proceeds to the Company from the exercise of the warrants were approximately \$4.7 million, prior to deducting placement agent fees and estimated offering expenses.

In connection with the execution of the Inducement Letter, the Company entered into a waiver related to the 2023 Notes' SPA it had entered into as of October 23, 2023. The SPA contained restrictions on the Company's ability to undertake certain transactions, which included entering into the Inducement Letter. The Waiver permitted the Company to enter into the Inducement Letter but required repayment of the remaining \$0.5 million of investor held notes issued under the SPA with a premium of \$0.5 million following closing of the inducement transaction.

The Company utilized an exclusive placement agent for the 2024 Warrant Inducement and incurred approximately \$0.3 million in legal fees and other closing costs. Additionally, the Company issued to the placement agent as compensation unregistered warrants to purchase up to 252,123 shares of Common Stock, equal to 7.0% of the aggregate number of shares of Common Stock (or warrants) placed in the transaction. The placement agent warrants expire on May 12, 2028, and have an exercise price of \$1.6375 per share of Common Stock (equal to 125% of the reduced exercise price per Existing Warrant).

#### *2024 Registered Direct Offering and 2024 August Warrant Inducement*

In August 2024, the Company entered into a definitive Securities Purchase Agreement with certain institutional investors, pursuant to which the Company agreed to issue and sell in a registered direct offering, (i) an aggregate of 2,490,798 shares of common stock of the Company, par value \$0.0001 per share at an offering price of \$0.47 per share, (ii) pre-funded warrants to purchase up to 1,062,396 shares of Common Stock, at a price per pre-funded warrant equal to \$0.4699, the price per share less \$0.0001, for gross proceeds of approximately \$1.67 million before the deduction of placement agent fees and offering expenses. The pre-funded warrants were subsequently exercised in full and were not outstanding as of September 30, 2024.

The Company also entered into an inducement agreement with certain warrant holders for the exercise of certain outstanding warrants to purchase up to an aggregate of 7,203,504 shares of common stock of the Company originally issued in February 2024, having an exercise price of \$1.06 per share, at a reduced exercise price of \$0.47 per share. The Company also agreed to amend certain existing warrants to purchase up to an aggregate of 2,000,000 shares of common stock that were previously issued in November 2023 and have an exercise price of \$1.5675 per share such that the amended warrants will have a reduced exercise price of \$0.47 per share effective upon the closing of the offering and will be exercisable from the date on which stockholder approval is received with respect to the issuance of the shares of common stock issuable upon exercise of such warrants.

In a concurrent private placement, pursuant to the terms of the inducement agreement and Securities Purchase Agreement, the Company also agreed to issue and sell unregistered warrants to purchase up to 28,716,900 shares of common stock. The warrants have an exercise price of \$0.47 per share and are exercisable from the date on which stockholder approval is received with respect to the issuance of the shares of common stock issuable upon exercise of the warrants. One half of the warrants will expire eighteen months after they are exercisable and the other half will expire five years after they are exercisable. The warrants contain customary anti-dilution adjustments to the exercise price, including for share splits, share dividends, rights offering and pro rata distributions.

The Company agreed to pay the placement agent a cash fee equal to 7% of the aggregate gross proceeds of the offerings or \$354,000. The Company also agreed to pay the placement agent \$100,950 for expenses. The Company also issued to the placement agent warrants to purchase up to 752,969 shares of common stock. These warrants have an exercise price equal to \$0.5875 per share and are exercisable for five years from the commencement of sales in the Offerings.

### **Components of Our Operating Results**

#### ***Revenue***

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

We have received funding under federal grants from the NIH through NIDA. In September 2018 and August 2024, we were awarded research and development grants related to the development of our MPAR® overdose prevention technology. In September 2019, we were awarded a second research and development grant related to the development of our TAAP/MPAR abuse deterrent technology for Opioid Use Disorder (“OUD”). Grant funds are awarded annually through a Notice of Award which contains certain terms and conditions including, but not limited to, complying with the grant program legislation, regulation and policy requirements, complying with conditions on expenditures of funds with respect to other applicable statutory requirements such as the federal appropriations acts, periodic reporting requirements, and budget requirements.

#### ***Operating Expenses***

##### *Research and Development Expenses*

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

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

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

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

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

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

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

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

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

#### *General and Administrative Expenses*

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

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

#### ***Other Income (Expense)***

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

The 2022 Notes were accounted for under ASC 480 – *Distinguishing Liabilities from Equity*, due to share settlement features contained within the notes. We used a discounted cash flow model and a Monte Carlo simulation to estimate the fair value of the notes, both of which rely on unobservable Level 3 inputs. Changes in the fair value of the notes are recognized through earnings for each reporting period.

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

We use a Black-Scholes option pricing model to estimate the fair value of the liability classified warrants. Changes in the fair value of the warrants are recognized through earnings for each reporting period.

### *Interest Expense*

Interest expense consists of interest accrued on our financed directors' and officers' insurance, and accumulated interest from the 2023 Notes based on the stated interest rate. In addition, the 2023 Notes balances reflect amortization of the debt discount from the original issuance and a discount associated with the warrant issuances and amortization of the associated debt issuance costs that are all recorded as interest expense. Interest expense related to the 2022 Notes was included in the estimate of fair value of the convertible notes.

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

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

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or our tax returns. Deferred tax assets and liabilities are determined based on difference between the financial statement carrying amounts and tax bases of existing assets and liabilities and for loss and credit carryforwards, which are measured using the enacted tax rates and laws in effect in the years in which the differences are expected to reverse. The realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of September 30, 2024 and December 31, 2023, we continue to maintain a full valuation allowance against all of our deferred tax assets based on our evaluation of all available evidence.

Beginning in 2022, the Tax Cuts and Jobs Act, or the Tax Act, eliminated the option to deduct research and development expenditures currently and requires taxpayers to capitalize and amortize them over five or fifteen years pursuant to Internal Revenue Code Section 174. This has not impacted our effective tax rate or our cash tax payable in 2024; however, if the requirement to capitalize Section 174 expenditures is not modified, it may also impact our effective tax rate and our cash tax liability in future years.

We file income tax returns in the United States federal tax jurisdiction and state jurisdictions and may become subject to income tax audit and adjustments by related tax authorities. Our tax return period for United States federal income taxes for the tax years since 2020 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, 2024 and 2023:

	Three Months Ended September 30,		
	2024	2023	Change
Federal grants	\$ 3,418,853	\$ 435,380	\$ 2,983,473
Operating expenses:			
Research and development	1,690,674	1,914,970	(224,296)
General and administrative	1,083,433	1,227,724	(144,291)
Total operating expenses	<u>2,774,107</u>	<u>3,142,694</u>	<u>(368,587)</u>
Income (loss) from operations	644,746	(2,707,314)	3,352,060
Other income (expense):			
Change in fair value of liability classified warrants	6,403	17,223	(10,820)
Interest expense	(4,063)	(7,649)	3,586
Other income, net	14,683	6,934	7,749
Total other income (expenses), net	<u>17,023</u>	<u>16,508</u>	<u>515</u>
Net income (loss)	661,769	(2,690,806)	3,352,575
Net income (loss) attributable to noncontrolling interests	-	(1,235)	1,235
<b>Net income (loss) attributable to common stockholders</b>	<u>\$ 661,769</u>	<u>\$ (2,689,571)</u>	<u>\$ 3,351,340</u>

#### Federal grant funding

Funding from federal grants for the three months ended September 30, 2024 and 2023 totaled \$3.4 million and \$0.4 million, respectively. The increase is due to the timing of research activities eligible for funding, with increased activities under the OUD grant following the selection of a lead drug candidate in June 2024 and funding under the newly awarded MPAR grant commencing in September 2024. We expect revenue from federal grants to decrease in coming quarters due to the completion of the OUD grant in August 2024 and the timing of research activities under the MPAR grant.

#### Research and development expenses

Research and development expenses for the three months ended September 30, 2024 and 2023 were \$1.7 million and \$1.9 million, respectively, representing a decrease of \$0.2 million. The decrease was primarily the result of reduced 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 increase from current levels with the availability of funding from the new MPAR grant.

#### General and administrative expenses

General and administrative expenses for the three months ended September 30, 2024 and 2023 were \$1.1 million and \$1.2 million, respectively, representing an decrease of \$0.1 million. We expect future general and administrative expenses to approximate current levels.

#### Other income and expense

Other income and expense for the three months ended September 30, 2024, consisted primarily of interest income from cash and cash equivalents. The comparative period for 2023 consisted primarily of changes in fair value associated with the Company's liability-classified warrants.

## Results of Operations

### Comparison of the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		
	2024	2023	Change
Federal grants	\$ 3,906,372	\$ 1,715,488	\$ 2,190,884
Operating expenses:			
Research and development	3,416,807	5,354,713	(1,937,906)
General and administrative	3,643,223	3,923,277	(280,054)
Total operating expenses	<u>7,060,030</u>	<u>9,277,990</u>	<u>(2,217,960)</u>
Loss from operations	(3,153,658)	(7,562,502)	4,408,844
Other income (expense):			
Change in fair value of convertible notes	-	146,479	(146,479)
Change in fair value of liability classified warrants	23,175	279,873	(256,698)
Interest expense	(1,279,691)	(9,146)	(1,270,545)
Other income (expense), net	(12,413)	23,382	(35,795)
Total other income (expense), net	<u>(1,268,929)</u>	<u>440,588</u>	<u>(1,709,517)</u>
Net loss	(4,422,587)	(7,121,914)	2,699,327
Net loss attributable to noncontrolling interests	(74)	(12,236)	12,162
Deemed dividend related to warrants down round provision	290	12,038	(11,748)
<b>Net loss attributable to common stockholders</b>	<u>\$ (4,422,803)</u>	<u>\$ (7,121,716)</u>	<u>\$ 2,698,913</u>

#### Federal grant funding

Funding from federal grants for the nine months ended September 30, 2024 and 2023 totaled \$3.9 million and \$1.7 million, respectively. The difference is due to the timing of research activities eligible for funding, with increased activities under the OUD grant following the selection of a lead drug candidate in June 2024 and funding under the newly awarded MPAR grant which began in September 2024.

#### Research and development expenses

Research and development expenses for the nine months ended September 30, 2024 and 2023 were \$3.4 million and \$5.4 million, respectively, representing a decrease of \$2.0 million. The decrease was primarily the result of reduced external research and development costs related to clinical and pre-clinical programs for PF614 and PF614-MPAR, with decreased clinical trial activity for both programs in the 2024 period. We do not currently track expenses on a program-by-program basis.

#### General and administrative expenses

General and administrative expenses for the nine months ended September 30, 2024 and 2023 were \$3.6 million and \$3.9 million, respectively, representing a decrease of \$0.3 million.

#### Other income and expense

Other income and expense for the nine months ended September 30, 2024, consisted primarily of interest expense associated with the amortization of the original issue discount and the debt issuance costs for the 2023 Notes and represented a net change in other income and expense of \$1.3 million compared to the nine months ended September 30, 2023. The comparative period for 2023 consisted primarily of changes in fair value associated with the 2022 Notes and the Company's liability-classified warrants.

## Liquidity and capital resources

### Sources of liquidity and capital

As of September 30, 2024, we had \$4.2 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 the foreseeable future. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all.

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

The remaining cash funding under the MPAR federal research grant totaled \$14 million at September 30, 2024 and is expected to be utilized by May 31, 2027. Pursuant to the terms and conditions, 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.

### Going Concern

We have generated limited revenues and have incurred significant operating losses since our inception. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Without capital raised through financing transactions, existing cash resources are sufficient to allow us to fund current planned operations into the first quarter of 2025, which raises substantial doubt about the Company's ability to continue as a going concern.

### Cash flows

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

	Nine Months Ended September 30,	
	2024	2023
Net cash used in operating activities	\$ (6,738,610)	\$ (8,978,107)
Net cash provided by financing activities	9,768,598	7,294,786
Net increase (decrease) in cash and cash equivalents	\$ 3,029,988	\$ (1,683,321)

### Operating activities

During the nine months ended September 30, 2024 and 2023, we used cash in operating activities of \$6.7 million and \$9.0 million, respectively. The decrease primarily resulted from the timing of vendor invoicing and payments and a reduction in research and development activities in the 2024 period.

### Financing activities

During the nine months ended September 30, 2024, net cash provided by financing activities was \$9.8 million, primarily consisting of net proceeds from the August 2024 public offering \$1.7 million, warrant exercises and the warrant inducement, net transaction costs \$8.9 million, less repayment of convertible notes of \$0.5 million and financed insurance premiums of \$0.3 million. During the nine months ended September 30, 2023, net cash provided by financing activities was \$7.3 million, primarily consisting of proceeds from 2023 February and 2023 May offerings of \$9.1 million, net of transaction costs of \$0.4 million and the repayment of financed insurance premiums of \$0.3 million and cash payment of 2022 Notes of \$1.0 million.

### *Funding requirements*

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

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, we have incurred, and will continue to incur, additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other expenses. The timing and amount of our operating expenditures will depend largely on our ability to:

- advance preclinical development of our early-stage programs and clinical trials of our product candidates;
- manufacture, or have manufactured on our behalf, preclinical and clinical drug material and develop processes for late 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.

### ***Commitments***

Our commitments as of September 30, 2024, included approximately \$13.3 million related to open purchase orders and contractual obligations that occurred in the ordinary course of business, including commitments with contract research organizations for multi-year pre-clinical and clinical research studies. Although open purchase orders are considered enforceable and legally binding, the terms generally allow us the option to cancel, reschedule, and adjust requirements based on our business needs prior to the delivery of goods or the performance of services.

### ***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 because of many factors, including:

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

## **Critical Accounting Policies and Significant Judgments and Estimates**

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

While our significant accounting policies are described in more detail in Note 3 to our audited consolidated financial statements included in our 2023 Annual Report on Form 10-K, we believe that the following accounting policy is the most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

### ***Accrued Research and Development Expenses***

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

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

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

### **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.

### **Smaller reporting company status**

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.**

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

***Interest Rate Risk***

Our cash and cash equivalents as of September 30, 2024, 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 SEC, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) as of September 30, 2024. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of September 30, 2024. 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.

**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 2023 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.

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

On August 28, 2024, in a private placement held concurrently with (i) a registered offering and (ii) an inducement offering to certain warrant holders for the exercise of outstanding warrants, pursuant to the terms of an inducement agreement and a Securities Purchase Agreement, the Company agreed to issue and sell unregistered warrants to purchase up to 28,716,900 shares of common stock. The warrants have an exercise price of \$0.47 per share and are exercisable from the date on which stockholder approval is received with respect to the issuance of the shares of common stock issuable upon exercise of the warrants. One half of the warrants will expire eighteen months after they are exercisable and the other half will expire five years after they are exercisable. The warrants contain customary anti-dilution adjustments to the exercise price, including for share splits, share dividends, rights offering and pro rata distributions.

The Company agreed to pay H.C. Wainwright & Co., LLC, the exclusive placement agent for the aforementioned transactions (“Wainwright”), a cash fee equal to 7% of the aggregate gross proceeds of the offerings or \$354,000. The Company also agreed to pay the placement agent \$100,950 for expenses. The Company also issued to the placement agent warrants to purchase up to 752,969 shares of common stock. These warrants have an exercise price equal to \$0.5875 per share and are exercisable for five years from the commencement of sales in the Offerings.

The unregistered warrants to purchase up to 28,716,900 shares of common stock were sold to the institutional investors identified in the Company’s Registration Statement on Form S-3 (333-282563) and the unregistered placement agent warrants to purchase up to 752,969 shares of common stock were issued to the affiliates of Wainwright identified in the same Registration Statement. The shares of common stock issued upon exercise of the unregistered warrants and unregistered placement agent warrants were registered in that Registration Statement

### 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>
3.2(b)	<a href="#"><u>Amendment, effective November 1, 2024, to Amended and Restated Bylaws of Ensysce Biosciences, Inc. (incorporated by reference to Exhibit 3.2(b) filed with the registrant's Current Report on Form 8-K (File No. 001-38306) on October 18, 2024).</u></a>
31.1*	<a href="#"><u>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.</u></a>
31.2*	<a href="#"><u>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.</u></a>
32.1*	<a href="#"><u>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.</u></a>
32.2*	<a href="#"><u>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.</u></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 12, 2024

*/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 12, 2024

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

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**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 12, 2024

/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, 2024, 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 12, 2024

*/s/ Lynn Kirkpatrick*

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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, 2024, 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 12, 2024

*/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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