

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

Form 10-Q

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

For the quarterly period ended: September 30, 2025

OR

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

For the transition period from to

Commission File Number 001-38306

ENSYSCE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

82-2755287

(I.R.S. Employer
Identification No.)

**7946 Ivanhoe Avenue, Suite 201
La Jolla, California**

(Address of principal executive offices)

92037

(Zip Code)

(858) 263-4196

(Registrant's telephone number, including area code)

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

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

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

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

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

Large accelerated filer ☐

Non-accelerated filer ☒

Accelerated filer ☐

Smaller reporting company ☒

Emerging growth company ☐

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

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

Registrant had 3,541,262 shares of common stock outstanding as of November 10, 2025.

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 common stock will be delisted from Nasdaq if we are not able to maintain compliance with applicable listing standards;
- the risk that our lead product candidate PF614 and PF614-MPAR may not be successful in limiting or impeding abuse, overdose, or misuse or providing additional safety upon commercialization;
- reliance by us on third-party contract research organizations, or CROs, for our research and development activities and clinical trials;
- the need for substantial additional funding to complete the development and commercialization of our product candidates;
- the risk 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 our business, operations, clinical development plans and timelines, and supply chain could be adversely affected by the effects of health epidemics
- the risk that we will be unable to obtain and maintain sufficient intellectual property protection for its investigational products or will infringe the intellectual property protection of others;
- the loss of key members of our management team;
- changes in our regulatory environment;
- the ability to attract and retain key scientific, medical, commercial, or management personnel;
- changes in our industry;
- our ability to remediate any material weaknesses or maintain effective internal controls over financial reporting;
- potential litigation associated with the Business Combination Transactions;
- 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, 2024, and other filings with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should any of the assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Moreover, the occurrence of the events described in the "Risk Factors" in our Annual Report on Form 10-K may adversely affect Ensysce. Ensysce will not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

GLOSSARY

Definitions:

2021 Notes	The senior secured convertible promissory notes in the aggregate original principal amount of \$15.9 million, sold in two closings on September 24, 2021, and November 5, 2021, respectively, pursuant to the Securities Purchase Agreement entered into on September 24, 2021
2021 Omnibus Incentive Plan	Ensysce Biosciences, Inc. Amended and Restated 2021 Omnibus Incentive Plan (“Plan”)
2022 Notes	The senior secured convertible promissory notes in the aggregate original principal amount of \$8.5 million, sold in two closings on June 30, 2022, and August 8, 2022, respectively, pursuant to the Securities Purchase Agreement entered into on June 30, 2022
2023 Notes	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
2023 May Offering	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
2024 February Warrant Inducement	The Company’s February 2024 transaction including the cash exercise of certain existing warrants at a reduced price and the issuance of new warrants
2024 August Warrant Inducement	The Company’s August 2024 transaction including the cash exercise of certain existing warrants at a reduced price and the issuance of new warrants
August Inducement Letter	Inducement offer letter entered into with certain holders of existing warrants to purchase 480,234 shares of the Company’s common stock (issued in February of 2024) to reduce the exercise price from \$15.90 per share to \$7.05 per share. The Company also agreed to amend certain existing warrants to purchase up to an aggregate of 133,334 shares of common stock that were previously issued in November 2023 and had an exercise price of \$23.51 per share such that the amended warrants have a reduced exercise price of \$7.05 per share.
2025 Registered Direct Offering	A definitive Securities Purchase Agreement with certain institutional investors, pursuant to which the Company agreed to issue and sell in a registered direct offering shares of common stock and pre-funded warrants for an aggregate amount of \$1.1 million.
2025 March Warrant Offering	An agreement by the Company to issue and sell unregistered warrants of Common Stock, Series A-5, and Series A-6 warrants to purchase shares of Common Stock
2025 April Warrant Inducement	The Company’s April 2025 Inducement offer letter entered into with certain holders of existing warrants to purchase 630,376 shares of the Company’s common stock (issued in March of 2025) and the issuance of new warrants exercisable for an aggregate of up to 1,260,752 shares of common stock with an exercise price of \$1.90 per share.
CMOs	Contract manufacturing organizations
Company	Ensysce Biosciences, Inc. and its consolidated subsidiaries
Covistat	A subsidiary renamed EBIR, Inc.
CROs	Contract research organizations
EB	Ensysce Biosciences, Inc. prior to its merger with Signature Acquisition Corp. pursuant to the EB-ST Agreement.
EBIR	Previously known as Covistat, Inc., EBIR, Inc. is a clinical stage pharmaceutical company that is developing a compound utilized in the Company’s overdose protection program for the treatment of COVID-19 and 79.2%-owned subsidiary of the Company
EB-ST Agreement	Agreement and Plan of Merger, dated as of December 28, 2015, by and among Signature, SAQ, and EB
Ensysce	Ensysce Biosciences, Inc.
Exchange Act	Securities Exchange Act of 1934, as amended

Definitions:

FDA	United States Food and Drug Administration
Former Ensysce	Ensysce Biosciences, Inc., a Delaware corporation, prior to the consummation of the merger with and into Merger Sub
GAAP	Generally Accepted Accounting Principles in the United States of America
JOBS Act	Jumpstart Our Business Startups Act of 2012
LACQ	Leisure Acquisition Corp., a Delaware Corporation
Merger	The merger of Merger Sub with and into Former Ensysce, with Former Ensysce continuing as the surviving entity and a wholly owned subsidiary of LACQ, which changed its name to Ensysce Biosciences, Inc. following consummation of the Merger.
Merger Sub	EB Merger Sub, Inc., a Delaware corporation, a wholly-owned subsidiary of LACQ prior to the consummation of the Merger
MPAR Grant	Research and development grant related to the development of its MPAR [®] overdose prevention technology awarded to the Company by NIH through NIDA in September 2018
Nasdaq	The Nasdaq Stock Market LLC
NIDA	National Institute of Drug Abuse
NIH	National Institutes of Health
ODU Grant	Research and development grant related to the development of its TAAP/MPAR [®] abuse deterrent technology for Opioid Use Disorder awarded to the Company by NIH/NIDA in September 2019
Registered Direct Offering	August 2024 registered direct offering of common stock (236,880 shares), private placement warrants (to purchase up to 473,760 shares) and the cash exercise of certain existing warrants (480,234 warrant shares) at a reduced price and the issuance of new warrants (to purchase up to 1,440,701 shares).
SAQ	Signature Acquisition Corp., a wholly-owned subsidiary of Signature
SEC	U.S. Securities and Exchange Commission
Securities Act	Securities Act of 1933, as amended
Securities Purchase Agreement	The Securities Purchase Agreement, in September 2021, June 2022, October 2023, August 2024, or March 2025, as the context dictates, by and between Ensysce and the institutional investors party thereto
Signature	Signature Therapeutics Inc.
SPA	The Securities Purchase Agreement, in September 2021, June 2022, October 2023, August 2024, or March 2025, as the context dictates, by and between Ensysce and the institutional investors party thereto
TAAP	Trypsin Activated Abuse Protection

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Ensysce Biosciences, Inc.
Consolidated Balance Sheets

	September 30, 2025 (Unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,673,218	\$ 3,502,077
Unbilled receivable	4,411	124,115
Prepaid expenses and other current assets	1,250,641	1,718,490
Total current assets	2,928,270	5,344,682
Property and equipment, net	123,643	-
Other assets	127,551	252,550
Total assets	\$ 3,179,464	\$ 5,597,232
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 463,458	\$ 1,357,079
Accrued expenses and other liabilities	1,453,555	548,458
Notes payable and accrued interest	387,702	301,660
Total current liabilities	2,304,715	2,207,197
Long-term liabilities:		
Other long-term liabilities	35	10,096
Total long-term liabilities	35	10,096
Total liabilities	\$ 2,304,750	\$ 2,217,293
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, \$0.0001 par value, 1,500,000 shares authorized, no shares issued and outstanding at September 30, 2025 and December 31, 2024	\$ -	\$ -
Common stock, \$0.0001 par value, 250,000,000 shares authorized at September 30, 2025 and December 31, 2024; 3,181,080 and 1,355,779 shares issued at September 30, 2025 and December 31, 2024, respectively; 3,181,074 and 1,355,773 shares outstanding at September 30, 2025 and December 31, 2024, respectively	320	136
Additional paid-in capital	138,155,394	133,252,585
Accumulated deficit	(136,952,351)	(129,544,299)
Total Ensysce Biosciences, Inc. stockholders' equity	1,203,363	3,708,422
Noncontrolling interests in stockholders' equity	(328,649)	(328,483)
Total stockholders' equity	874,714	3,379,939
Total liabilities and stockholders' equity	\$ 3,179,464	\$ 5,597,232

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,	
	2025	2024	2025	2024
Federal grants	\$ 493,104	\$ 3,418,853	\$ 3,184,314	\$ 3,906,372
Operating expenses:				
Research and development	2,954,909	1,690,674	6,763,866	3,416,807
General and administrative	1,279,290	1,083,433	3,879,569	3,643,223
Total operating expenses	4,234,199	2,774,107	10,643,435	7,060,030
Income (loss) from operations	(3,741,095)	644,746	(7,459,121)	(3,153,658)
Other income (expense):				
Change in fair value of liability classified warrants	998	6,403	10,061	23,175
Interest expense, net	(6,369)	(4,063)	(13,385)	(1,279,691)
Other income and expense, net	17,338	14,683	54,227	(12,413)
Total other income (expense), net	11,967	17,023	50,903	(1,268,929)
Net income (loss)	\$ (3,729,128)	\$ 661,769	\$ (7,408,218)	\$ (4,422,587)
Net loss attributable to noncontrolling interests	-	-	(166)	(74)
Deemed dividend related to warrants down round provision	-	-	-	290
Net income (loss) attributable to common stockholders	<u>\$ (3,729,128)</u>	<u>\$ 661,769</u>	<u>\$ (7,408,052)</u>	<u>\$ (4,422,803)</u>
Net income (loss) per basic and diluted share:				
Net income (loss) per share attributable to common stockholders, basic and diluted	\$ (1.29)	\$ 1.00	\$ (3.42)	\$ (8.52)
Weighted average common shares outstanding, basic and diluted	<u>2,886,059</u>	<u>659,361</u>	<u>2,168,247</u>	<u>518,838</u>

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

Ensysce Biosciences, Inc.
Consolidated Statements of Changes in Stockholders' Equity
(Unaudited)

	Stockholders' Equity					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Noncontrolling interests	Total
	Number of Shares	Amount				
Balance on June 30, 2024	543,412	\$ 54	\$ 128,449,460	\$ (126,641,646)	\$ (328,483)	\$ 1,479,385
Public offering	236,881	24	1,669,977	-	-	1,670,001
Issuance of common stock upon inducement of warrants	144,412	14	3,385,633	-	-	3,385,647
Transaction costs associated with public offering and warrant inducement	-	-	(637,894)	-	-	(637,894)
Stock-based compensation	-	-	20,819	-	-	20,819
Reversed stock-split rounding adjustment	(4)	-	-	-	-	-
Net income	-	-	-	661,769	-	661,769
Balance on September 30, 2024	924,701	\$ 92	\$ 132,887,995	\$ (125,979,877)	\$ (328,483)	\$ 6,579,727
Balance on June 30, 2025	2,393,256	\$ 241	\$ 136,612,043	\$ (133,223,223)	\$ (328,649)	\$ 3,060,412
Issuance of common stock upon exercise of warrants	787,818	79	1,496,775	-	-	1,496,854
Consultant settlement	-	-	718	-	-	718
Stock-based compensation	-	-	45,858	-	-	45,858
Net loss	-	-	-	(3,729,128)	-	(3,729,128)
Balance on September 30, 2025	3,181,074	\$ 320	\$ 138,155,394	\$ (136,952,351)	\$ (328,649)	\$ 874,714
Balance on December 31, 2023	209,739	21	\$ 121,234,195	\$ (121,557,074)	(328,409)	(651,267)
Settlement of restricted stock units	5	-	-	-	-	-
Conversion of convertible notes	49,702	5	1,168,595	-	-	1,168,600
Public offering	236,881	24	1,669,977	-	-	1,670,001
Issuance of common stock upon exercise of warrants	88,262	9	2,075,210	-	-	2,075,219
Issuance of common stock upon warrant inducement, net of issuance cost	340,121	33	8,103,910	-	-	8,103,943
Transaction costs associated with warrant inducement	-	-	(1,444,756)	-	-	(1,444,756)
Stock-based compensation	-	-	80,574	-	-	80,574
Reversed stock-split rounding adjustment	(9)	-	-	-	-	-
Deemed dividend related to warrant down round provision	-	-	290	(290)	-	-
Net loss	-	-	-	(4,422,513)	(74)	(4,422,587)
Balance on September 30, 2024	924,701	\$ 92	\$ 132,887,995	\$ (125,979,877)	\$ (328,483)	\$ 6,579,727
Balance on December 31, 2024	1,355,773	136	\$ 133,252,585	\$ (129,544,299)	(328,483)	3,379,939
Public offering	239,594	25	1,099,982	-	-	1,100,007
Issuance of common stock upon exercise of warrants	935,331	94	1,887,615	-	-	1,887,709
Transaction costs associated with public offering	-	-	(204,193)	-	-	(204,193)
Issuance of common stock upon warrant inducement, net of issuance cost	630,376	63	2,199,949	-	-	2,200,012
Transaction costs associated with warrant inducement	-	-	(297,021)	-	-	(297,021)
Consultant compensation	20,000	2	63,730	-	-	63,732
Stock-based compensation	-	-	152,747	-	-	152,747
Net loss	-	-	-	(7,408,052)	(166)	(7,408,218)
Balance on September 30, 2025	3,181,074	\$ 320	\$ 138,155,394	\$ (136,952,351)	\$ (328,649)	\$ 874,714

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,	
	2025	2024
Cash flows from operating activities:		
Net loss	\$ (7,408,218)	\$ (4,422,587)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accrued interest	9,268	33,175
Amortization of original issue discount and debt issuance costs	-	1,197,200
Change in fair value of liability classified warrants	(10,061)	(23,175)
Consultant compensation	253,731	-
Stock-based compensation	152,747	80,574
Changes in operating assets and liabilities:		
Unbilled receivable	119,704	(1,685,244)
Prepaid expenses and other assets	780,894	(1,729,252)
Accounts payable	(893,621)	(57,666)
Accrued expenses and other liabilities	715,097	(131,635)
Net cash used in operating activities	(6,280,459)	(6,738,610)
Cash flows from investing activities:		
Investment in property and equipment	(123,643)	-
Net cash used in investing activities	(123,643)	-
Cash flows from financing activities:		
Proceeds from public offerings	1,100,007	1,670,001
Proceeds from warrant exercises	1,887,709	2,075,219
Proceeds from warrant inducement, net of issuance costs	2,200,012	8,103,943
Transaction costs from public offerings	(204,193)	-
Transaction costs associated with warrant inducements	(297,021)	(1,319,115)
Repayment of convertible notes	-	(485,190)
Repayment of financed insurance premiums	(111,271)	(276,260)
Net cash provided by financing activities	4,575,243	9,768,598
Increase (decrease) in cash and cash equivalents	(1,828,859)	3,029,988
Cash and cash equivalents beginning of period	3,502,077	1,123,604
Cash and cash equivalents end of period	\$ 1,673,218	\$ 4,153,592
Supplemental disclosure of non-cash investing and financing activities:		
Incremental fair value of August 2024 Warrant Inducement	\$ -	\$ 10,210,616
Incremental fair value of February 2024 Warrant Inducement	\$ -	\$ 5,167,372
Incremental fair value of April 2025 Warrant Inducement	\$ 3,483,420	\$ -
Conversion of convertible notes into common stock	\$ -	\$ 1,168,600
Transaction costs from warrant inducement and public offering included in accounts payable	\$ -	\$ 12,641
Transaction costs from public offerings	\$ -	\$ -
Deemed dividend related to warrants down round provision	\$ -	\$ 290
Financed insurance premiums	\$ 188,046	\$ 235,155

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

Ensysce Biosciences, Inc.
Notes to the Consolidated Financial Statements
(Unaudited)

NOTE 1 – ORGANIZATION AND PRINCIPAL ACTIVITIES

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

In 2020, the Company commenced an initiative to develop a therapeutic for the treatment of certain coronavirus infections through the formation of a separate entity, EBIR, a Delaware corporation. Pursuant to the articles of incorporation, EBIR was authorized to issue 1,000,000 shares of common stock, \$0.001 par value per share, and 100,000 shares of preferred stock, \$0.001 par value per share. Ensysce is a 79.2% stockholder in EBIR, with 19.8% and 1.0% of the shares held by certain key personnel of the Company and an unrelated party, respectively. The non-Ensysce owned shares and the activity are reflected on the financial statements as noncontrolling interests.

NOTE 2 - BASIS OF PRESENTATION

The consolidated financial statements have been prepared in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”) and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”). The consolidated financial statements include the accounts of Ensysce Biosciences, Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated in the consolidation.

Reverse Stock Split

In December 2024, the Company completed a 1-for-15 reverse split of its outstanding common stock.

All references in these consolidated financial statements to shares and per share amounts in all periods have been retrospectively restated to reflect the effects of both reverse splits noted above. The number of authorized shares and the par value of the shares did not change as a result of the reverse stock splits.

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, would be sustained on a continuing basis. Product development activities, clinical and pre-clinical testing, and commercialization of the Company’s product candidates are necessary to develop the Company’s products and will require significant additional financing. There can be no assurance the Company will be able to obtain such funds. These matters, among others, raise substantial doubt about the Company’s ability to continue as a going concern.

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 a concentration in accounts payable, as two and three research and development vendors made up greater than 10% individually, and 56% and 74% in aggregate, of the outstanding accounts payable balance as of September 30, 2025, and December 31, 2024, respectively.

Segments

The Company operates and manages its business as one reportable and operating segment. Operating segments are defined as components of an enterprise where separate financial information is evaluated regularly by the chief operating decision maker ("CODM") in deciding how to allocate resources and assess performance. The Company's CODM is the Chief Executive Officer, who reviews consolidated financial information on a company-wide basis for purposes of allocating resources and assessing financial performance and does not regularly review expenses or financial results on a more granular level.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over an estimated useful life of five years. As of September 30, 2025, property and equipment consists of laboratory equipment that has not been placed in service, as such there is no depreciation expense recognized in the three and nine months ended September 30, 2025, and 2024.

Fair Value Measurement

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

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

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

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

As of September 30, 2025, and December 31, 2024, 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 2022 Notes. The warrants were liability classified due to certain cash settlement features and included in "Other long-term liabilities" on the consolidated balance sheets. The Company uses a Black Scholes model to estimate the fair value of the warrants. Changes in the fair value of the warrants are recognized in other income (expense) for each reporting period. Refer to Note 9 for additional details of the warrants.

The following tables present assets and liabilities measured and recorded at fair value on the Company's consolidated balance sheet as of September 30, 2025, and December 31, 2024.

September 30, 2025				
	Total	Level 1	Level 2	Level 3
Liability classified warrants	\$ 35	\$ -	\$ -	\$ 35
Total	\$ 35	\$ -	\$ -	\$ 35

December 31, 2024				
	Total	Level 1	Level 2	Level 3
Liability classified warrants	\$ 10,096	\$ -	\$ -	\$ 10,096
Total	\$ 10,096	\$ -	\$ -	\$ 10,096

The following table summarizes the change in fair value of the Company's Level 3 liabilities for the year ended September 30, 2025 (no level 3 assets as of September 30, 2025):

	Liability classified warrants
Fair value, December 31, 2024	\$ 10,096
Change in fair value	(10,061)
Fair value, September 30, 2025	\$ 35

Federal Grants

In September 2018, the NIH through NIDA awarded the Company a research and development 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 total funding of \$15.1 million through May 2027, as adjusted. As September 30, 2025, remaining funding under the grant is \$8.9 million.

In September 2019, the NIH/NIDA awarded the Company a second research and development grant related to the development of its TAAP/MPAR abuse deterrent technology for 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,	
	2025	2024	2025	2024
MPAR	\$ 493,104	\$ 1,782,805	\$ 3,184,314	\$ 1,782,805
TAAP/OUN	-	1,636,048	-	2,123,567
Total	<u>\$ 493,104</u>	<u>\$ 3,418,853</u>	<u>\$ 3,184,314</u>	<u>\$ 3,906,372</u>

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

Research and Development Costs

The Company’s research and development expenses consist primarily of third-party research and development expenses, consulting expenses, preclinical 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 research and development and general and administrative expenses in the consolidated statements of operations.

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

Income Taxes

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

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

Earnings (loss) per Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Stock options	102,089	38,694	81,745	38,694
Warrants	3,590,293	1,255,358	3,000,380	879,657
Convertible Notes	2,316	9,187	6,871	9,187
Consultant Shares	4,600	-	4,600	-
Total	3,699,298	1,303,239	3,093,596	927,538

Recently Issued Accounting Pronouncements

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.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses (“ASU 2024-03”), which requires disclosure about the types of costs and expenses included in certain expense captions presented on the income statement. The new disclosure requirements are effective for the Company’s annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of this pronouncement on its related disclosures.

In November 2024, the FASB issued ASU 2024-04, “Debt – Debt with Conversion and other Options (Subtopic 470-20) “, which set forth to improve the relevance and consistency in the application of induced conversion guidance in Subtopic 470-20, Debt— Debt with Conversion and Other Options such as clarifying the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion. ASU 2024-04 is effective for all entities after December 15, 2025, 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, 2025	December 31, 2024
Prepaid research and development	\$ 692,170	\$ 1,342,461
Prepaid insurance	358,002	315,306
Other prepaid expenses	132,335	42,723
Other current assets	68,134	18,000
Total prepaid expenses and other current assets	<u>\$ 1,250,641</u>	<u>\$ 1,718,490</u>

NOTE 5 – OTHER ASSETS

Other assets consisted of the following:

	September 30, 2025	December 31, 2024
Prepaid insurance	\$ 125,000	\$ 250,000
Deposits	2,551	2,550
Total other assets	<u>\$ 127,551</u>	<u>\$ 252,550</u>

NOTE 6 – ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consisted of the following:

	September 30, 2025	December 31, 2024
Accrued research and development	\$ 958,165	\$ 324,521
Accrued consultant compensation	180,000	-
Accrued professional fees	142,568	88,995
Other accrued liabilities	172,822	134,942
Total accrued expenses and other liabilities	<u>\$ 1,453,555</u>	<u>\$ 548,458</u>

NOTE 7 - COMMITMENTS AND CONTINGENCIES

Purchase Commitments

As of September 30, 2025, the Company's commitments included an estimated \$7.3 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 funded by federal grants. 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, 2025, and December 31, 2024, 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.

Consultant Dispute

In April 2025, the Company entered into an agreement with a former independent contractor to resolve a dispute over payment. The Company denied the allegations but agreed to settle the matter. In connection with the settlement agreement, the Company issued 20,000 shares of common stock to the consultant in April 2025. As of September 30, 2025, the Company accrued a total settlement value of \$0.2 million.

Galephar Agreement

In January 2025, the Company entered into a product development and supply agreement with Galephar Pharmaceutical Research, Inc., a Puerto Rico specialty drug manufacturer ("Galephar"), to support the development, manufacture, packaging and testing of the Company's PF614 and PF614-MPAR drug products for use in clinical trials and potential future commercial launch.

Upon signing, the Company committed to issue 13,801 restricted shares of common stock (approximately 1% of shares outstanding), subject to vesting in three tranches upon achievement of specific operational and regulatory milestones. The Company accounts for this share grant as nonemployee share-based compensation under ASC 718. One-third of the shares vested immediately upon grant, and the remaining two-thirds will vest as services are performed. During the three and nine months ended September 30, 2025, the Company recognized \$0 and \$25,806 of stock-based compensation related to the one-third immediate vesting of 4,600 shares upon grant date. As of September 30, 2025, no shares have been issued.

The agreement also provides for milestone-based payments, to be settled in common stock (50% restricted, 50% freely tradeable), based on the trailing five-day average closing price at the time of each milestone achievement. Share-based expense for these milestone grants will be recognized as services are rendered. These awards are liability-classified until shares are issued, at which point they will be reclassified to equity. During the three and nine months ended September 30, 2025, the Company recognized \$50,000 and \$190,000 of research and development expense to be settled in shares that was related to milestone progression and is accrued under accrued expenses and other liabilities in the consolidated balance sheet. As of September 30, 2025, no shares have been issued.

Lease

The Company's current lease agreement (as amended) has a term that extends through October 31, 2026, with no option to renew. As of September 30, 2025, the future lease payments totaled \$39,826. The Company recognized total rent expense of \$9,088 and \$27,265 in the three and nine months ended September 30, 2025 and \$8,747 and \$26,242 in the three and nine months ended September 30, 2024.

NOTE 8 - NOTES PAYABLE

The following table provides a summary of the Company's outstanding debt as of September 30, 2025:

	Principal balance	Accrued interest	Net debt balance
2023 Notes	\$ 216,000	\$ 23,636	\$ 239,636
Financed insurance	148,066	-	148,066
Total	\$ 364,066	\$ 23,636	\$ 387,702

The following table provides a summary of the Company's outstanding debt as of December 31, 2024:

	Principal balance	Accrued interest	Net debt balance
2023 Notes	\$ 216,000	\$ 14,368	\$ 230,368
Financed insurance	71,292	-	71,292
Total	\$ 287,292	\$ 14,368	\$ 301,660

Interest expense

The interest expense recognized for financed insurance was \$3,208 and \$4,118 for the three months and nine months ended September 30, 2025 and \$4,063 and \$6,155 for the three and nine months ended September 30, 2024. Interest expense recognized for the 2023 Notes was \$3,161 and \$9,268 for the three and nine months ended September 30, 2025 and \$0 and \$1.3 million for the three and nine months ended September 30, 2024, which consists of amortization of the debt discount and debt issuance costs and accrued interest.

2023 Notes

In October 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 83,714 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 (i) additional warrants to purchase 167,427 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 December 31, 2024, the original debt discount and issuance costs were fully amortized to interest expense.

The warrants have an exercise price of \$23.5125, 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 December 31, 2024, the discount associated with the warrants was fully amortized to interest expense.

During 2024, the Company converted 49,702 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 9) 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, 2025, the remaining amount of the 2023 Notes relates to senior secured convertible promissory notes held by a Company board member (see Note 11).

Financed Insurance Premiums

In June 2025, the Company renewed and financed its directors' and officers' liability insurance in the amount of \$0.2 million. Monthly payments are scheduled from July 2025 through March 2026.

NOTE 9 - 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, 2025, and December 31, 2024, there were no shares of preferred stock issued and outstanding.

2025 April Warrant Inducement

In April 2025, the Company entered into an Inducement Letter with certain warrant holders for the exercise of certain outstanding warrants to purchase up to an aggregate of 630,376 shares of common stock of the Company, par value \$0.0001 per share. The warrants were issued in March 2025 and have an exercise price of \$3.24 share. The shares of common stock issuable upon exercise of such outstanding warrants are registered pursuant to an effective registration statement on Form S-3.

In consideration for the immediate exercise of the warrants for cash and the payment of an additional \$0.125 per new unregistered warrant (an additional \$157,594 included in the gross proceeds to the Company), pursuant to the Inducement Agreement, the Company agreed to issue and sell unregistered warrants to purchase shares of common stock. The new warrants (the "*Common Warrants*") are exercisable for an aggregate of up to 1,260,752 shares of common stock. The Common Warrants have an exercise price of \$1.90 per share and are immediately exercisable for shares of common stock. One half of the Common Warrants will expire after eighteen (18) months and the other half will expire after five (5) years. The gross proceeds to the Company from the exercise of the warrants and payment for Common Warrants was approximately \$2.2 million, prior to deducting placement agent fees and estimated offering expenses.

The Company utilized a placement agent for the 2025 April 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 44,126 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 April 24, 2030, and have an exercise price of \$4.05 per share of common stock. The closing of the offering occurred on April 24, 2025.

2025 Registered Direct Offering and 2025 March Warrant Offering

In March 2025, the Company entered into a definitive SPA with certain institutional investors, pursuant to which the Company agreed to issue and sell in a registered direct offering, (i) an aggregate of 239,594 shares of common stock, par value \$0.0001 per share at an offering price of \$3.49 per share, (ii) pre-funded warrants to purchase up to 75,594 shares of common stock, at a price per pre-funded warrant equal to \$3.4899, the price per share less \$0.0001, for gross proceeds of approximately \$1.1 million before the deduction of placement agent fees and offering expenses. The pre-funded warrants were fully exercised as of March 31, 2025, and the related common shares were issued in April 2025.

In a concurrent private placement, pursuant to the terms of the SPA, the Company also agreed to issue and sell unregistered warrants to purchase up to 315,188 shares of Common Stock (the “*Series A-5 Warrants*”), and Series A-6 warrants to purchase up to 315,188 shares of Common Stock (the “*Series A-6 Warrants*”), to purchase up to an aggregate 630,376 shares of Common Stock. The warrants have an exercise price of \$3.24 per share and are exercisable immediately. The Series A-5 Warrants will expire eighteen (18) months after issuance and the Series A-6 Warrants will expire five (5) years after issuance.

2024 Registered Direct Offering and 2024 August Warrant Inducement

In August 2024, the Company entered into a definitive SPA with certain institutional investors, pursuant to which the Company agreed to issue and sell in a registered direct offering, (i) an aggregate of 166,054 shares of common stock, par value \$0.0001 per share at an offering price of \$7.05 per share, (ii) pre-funded warrants to purchase up to 70,827 shares of common stock, at a price per pre-funded warrant equal to \$7.0485, the price per share less \$0.0015, for gross proceeds of approximately \$1.7 million before the deduction of placement agent fees and offering expenses. The pre-funded warrants were subsequently exercised in full.

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 480,234 shares of common stock of the Company originally issued in February 2024, having an exercise price of \$15.90 per share, at a reduced exercise price of \$7.05 per share. The Company also agreed to amend certain existing warrants to purchase up to an aggregate of 133,334 shares of common stock that were previously issued in November 2023 and have an exercise price of \$23.5125 per share such that the amended warrants will have a reduced exercise price of \$7.05 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 SPA, 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 50,200 shares of Common Stock. The placement agent warrants expire on August 28, 2029, and have an exercise price of \$8.8125 per share of Common Stock.

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 240,120 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 240,120 shares of Common Stock at a reduced exercise price of \$19.65 per share in consideration of the Company’s agreement to issue new unregistered Series A Warrants (the “*Series A Warrants*”) to purchase up to 240,120 shares of Common Stock and new unregistered Series B Warrants (the “*Series B Warrants*”) to purchase up to 240,120 shares of Common Stock (collectively, the “*New Warrant Shares*”). The Series A Warrants have an exercise price of \$15.90 per share and have a term equal to eighteen months from the date of issuance. The Series B Warrants have an exercise price of \$15.90 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 into 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 contemplated thereby. Refer to Note 8 for the details of the waiver fee and the application of the amounts to the outstanding notes and as a transaction cost of the warrant inducement.

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 16,811 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 \$24.5625 per share of Common Stock (equal to 125% of the reduced exercise price per Existing Warrant). The closing of the offering occurred on February 14, 2024.

Warrants

The following table provides a summary of outstanding warrants to purchase shares of common stock as of September 30, 2025:

Reference	Shares Underlying Outstanding Warrants	Exercise Price	Description	Classification
(a)	494,502	\$ 1.90 - \$4.05	April 2025 Warrants	Equity
(b)	22,063	\$ 4.3625	March 2025 Warrants	Equity
(c)	1,864,545	\$ 7.05 - \$8.8125	August 2024 Warrants	Equity
(d)	16,811	\$ 24.56	February 2024 Warrants	Equity
(e)	162,881	\$ 7.05 - \$23.51	2023 Notes Warrants	Equity
(f)	73,474	\$ 54.56 - \$41,400	Other Warrants	Equity & Liability
	<u>2,634,276</u>			

- (a) On April 24, 2025, the Company issued 1,304,878 equity classified warrants (Common Warrants and placement agent warrants) in connection with the Inducement Letter of the 2025 April warrant inducement. The Common Warrants have an exercise price of \$1.90 per share and are immediately exercisable for shares of common stock. One half of the Common Warrants will expire on October 26, 2026, and the other half will expire on April 24, 2030. The placement agent warrants were immediately exercisable with an exercise price of \$4.05 per share and expire on April 24, 2030. During the nine months ended September 30, 2025, a holder of the warrants exercised 810,376 warrants at an exercise price of \$1.90 per share.
- (b) On March 31, 2025, in connection with the 2025 Registered Direct Offering and 2025 March Warrant Offering, the Company issued equity classified warrants to purchase 652,439 shares to certain institutional investors and the placement agent. The warrants were issued in connection with the 2025 Registered Direct Offering and 2025 March Warrant Offering. The 630,376 investor warrants have an exercise price of \$3.24 per share. One half of the warrants will expire on October 1, 2026, and the other half will expire on March 31, 2030. The 22,063 placement agent warrants have an exercise price of \$4.3625 per share and expire on March 30, 2030. In connection with the 2025 April Warrant Inducement, 630,376 investor warrants were exercised. As of September 30, 2025, the placement agents remain outstanding.
- (c) 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 1,964,666 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 1,914,466 investor warrants have an exercise price of \$7.05 per share. One half of the warrants expire on May 21, 2026, and the other half expire on November 21, 2029. The 50,200 placement agent warrants have an exercise price of \$8.8125 per share and expire on August 28, 2029. In December 2024 and January 2025, investor warrants of 50,760 and 49,361, respectively, were exercised.

- (d) On February 12, 2024, the Company issued 497,047 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 \$15.90 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 \$24.56 per share and expire on May 12, 2028. In connection with the 2024 August Warrant Inducement, 480,236 Series A and Series B warrants were exercised. As of September 30, 2025, the placement agents remain outstanding.
- (e) On October 25, 2023, and November 28, 2023, the Company issued warrants to purchase 83,714 shares and 167,428 shares, respectively. The warrants were immediately exercisable with an exercise price of \$23.51 per share and expire on October 25, 2028, and November 28, 2028, respectively. In January 2024, a holder of the warrants exercised 88,261 warrants at an exercise price of \$23.51 per share. In August 2024, an inducement letter was issued to a holder of 133,334 warrants to reduce the exercise price from \$23.51 to \$7.05 per share.
- (f) At various dates from the Closing of the Business Combination through September 30, 2023, the Company assumed or issued a total of 73,474 warrants to provide holders the right to purchase common stock at exercise prices ranging from \$54.60 - \$41,400 per share. A total of 2,778 of the outstanding warrants are public warrants which trade on the OTC Pink Open Market under the ticker symbol ENSCW. A total of 2,901 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 10 - STOCK-BASED COMPENSATION

In connection with the Business Combination, the Company assumed the 2021 Omnibus Incentive Plan. In February 2025, the Company's Board approved an annual increase of 67,789 shares available for future grant under the 2021 Omnibus Plan ("Plan").

The Company recognized within general and administrative expense stock-based compensation expense of \$30,298 and \$103,431 for the three and nine months ended September 30, 2025 and \$14,497 and \$56,643 for the three and nine month ended September 30, 2024. The Company recognized stock-based compensation expense within research and development expense of \$66,278 and \$267,848 for the three and nine months ended September 30, 2025 and \$6,322 and \$23,931 for the three and nine months ended September 30, 2024.

Option Activity

During the nine months ended September 30, 2025, the Company granted stock options to purchase an aggregate of 64,000 shares of common stock to employees and members of the board of directors. The options vest over one to four years and have an exercise price of \$2.00 to \$3.12 per share.

The following table summarizes the Company's stock option activity during the nine months ended September 30, 2025:

	Options	Weighted average		Intrinsic value
		Exercise price	Remaining contractual life	
Outstanding at December 31, 2024	38,785	\$ 501.65	\$ 8.58	-
Granted	64,000	2.94	9.50	-
Exercised	-	-	-	-
Expired / Forfeited	-	-	-	-
Outstanding at September 30, 2025	102,785	\$ 191.13	\$ 8.87	-
Exercisable at September 30, 2025	64,768	300.39	-	-
Vested and expected to vest	102,785	\$ 191.13	\$ 8.87	-

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:

	September 30, 2025
Exercise price	\$ 2.00 - 3.12
Expected stock price volatility	114.21% - 141.65%
Expected term (years)	5.27 - 6.08
Risk-free interest rate	3.83% - 4.00%
Expected dividend yield	0%

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

The weighted-average grant date fair value of options granted during the nine months ended September 30, 2025, was \$2.63.

As of September 30, 2025, the Company had an aggregate of \$43,681 of unrecognized share-based compensation cost, which is expected to be recognized over the weighted average period of 0.88 years.

Shares Reserved for Future Issuance

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

	September 30, 2025
Awards outstanding under the Plan	102,785
Awards available for future grant under the Plan	14,385
Warrants outstanding	2,634,276
Shares for consultant compensation agreement outside the Plan	13,801
Total shares of common stock reserved for future issuance	<u>2,765,247</u>

NOTE 11 - RELATED PARTIES

As of September 30, 2025, the Company held a \$0.2 million senior secured convertible promissory note plus accrued interest and 29,547 warrants exercisable for common stock at \$23.51 per share issued to a board member in connection to the issuance of the 2023 Notes. The Company and the board member have entered into a forbearance agreement that will expire on April 25, 2026. 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.

NOTE 12 - SUBSEQUENT EVENTS

The Company has issued 360,188 shares of common stock for cash proceeds of \$0.7 million upon exercise of certain April 2025 warrants since September 30, 2025.

In November 2025, the Company completed a convertible preferred stock offering with gross proceeds of \$4 million and potentially \$16 million of additional funding through future tranches over the next 24 months. The preferred stock is convertible into common stock at a fixed conversion price of \$2.50 per share, with an alternate conversion price based upon average stock prices prior to conversion at the holder's option. The offering includes 50% warrant coverage on each tranche; 880,000 warrants were issued at an exercise price of \$2.50 in this initial tranche.

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 fear of and the potential for opioid misuse, abuse and overdose. Our lead product candidate, PF614, is an extended release TAAP prodrug of oxycodone. TAAP modification of prescription drugs removed the ability to crush, chew or manipulate and inject to achieve the effect of the medication more quickly than by swallowing. MPAR[®] adds a layer of overdose protection to each TAAP product.

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

Our lead product candidate, PF614, is in Phase 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 continue to incur net losses for the foreseeable future. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing development activities, particularly if and as we:

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

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

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

We have generated limited revenues and have incurred significant operating losses since our inception and 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. Without raising additional capital through a future offering, we believe that current cash on hand is sufficient to fund operations into the late fourth quarter of 2025. We based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “— *Liquidity and Capital Resources.*” Our future viability beyond the twelve months is dependent on our ability to raise additional capital to finance our operations.

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

2025 April Warrant Inducement

In April 2025, we entered into an Inducement Letter with certain warrant holders for the exercise of certain outstanding warrants to purchase up to an aggregate of 630,736 share of our common stock, par value \$0.0001 per share. The warrants were issued in March 2025 with an exercise price of \$3.24 share. The shares of common stock issuable upon exercise of such outstanding warrants are registered pursuant to an effective register statement on Form S-3.

In consideration for the immediate exercise of the warrants for cash and the payment of an additional \$0.125 per new unregistered warrant (an additional \$157,594 included in our gross proceeds), pursuant to the Inducement Agreement, we agreed to issue and sell unregistered warrants to purchase shares of common stock. The new warrants (the “Common Warrants”) are exercisable for an aggregate of up to 1,260,752 shares of common stock. The Common Warrants have an exercise price of \$1.90 per share and are immediately exercisable for shares of common stock. One half of the Common Warrants will expire after eighteen (18) months and the other half will expire after five (5) years. Our gross proceeds from the exercise of the warrants and payment for Common Warrants was approximately \$2.2 million, prior to deducting placement agent fees and estimated offering expenses.

We utilized a placement agent for the 2025 April Warrant Inducement and incurred approximately \$0.3 million in legal fees and other closing costs. Additionally, we issued to the placement agent as compensation unregistered warrants to purchase up to 44,126 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 April 24, 2030, and have an exercise price of \$4.05 per share of common stock. The closing of the offering occurred on April 24, 2025.

2025 Registered Direct Offering and 2025 March Warrant Offering

In March 2025, we entered into a definitive SPA with certain institutional investors, pursuant to which we agreed to issue and sell in a registered direct offering, (i) an aggregate of 239,594 shares of common stock, par value \$0.0001 per share at an offering price of \$3.49 per share, (ii) pre-funded warrants to purchase up to 75,594 shares of common stock, at a price per pre-funded warrant equal to \$3.4899, the price per share less \$0.0001, for gross proceeds of approximately \$1.1 million before the deduction of placement agent fees and offering expenses. The pre-funded warrants were fully exercised as of March 31, 2025, and the related common shares were issued in April 2025.

In a concurrent private placement, pursuant to the terms of the SPA, we also agreed to issue and sell unregistered warrants to purchase up to 315,188 shares of Common Stock (the “Series A-5 Warrants”), and Series A-6 warrants to purchase up to 315,188 shares of Common Stock (the “Series A-6 Warrants”), to purchase up to an aggregate 630,376 shares of Common Stock. The warrants have an exercise price of \$3.24 per share and are exercisable immediately. The Series A-5 Warrants will expire eighteen (18) months after issuance and the Series A-6 Warrants will expire five (5) years after issuance. The warrants contain customary anti-dilution adjustments to the exercise price, including for share splits, share dividends, rights offering and pro rata distributions.

We agreed to pay the placement agent a cash fee equal to 7% of the aggregate gross proceeds of the offerings or \$77,000. We also agreed to pay the placement agent \$65,950 for expenses. We also issued to the placement agent warrants to purchase up to 22,063 shares of common stock. These warrants have an exercise price equal to \$4.3625 per share and are exercisable for five years.

2024 Registered Direct Offering and 2024 August Warrant Inducement

In August 2024, we entered into a definitive SPA with certain institutional investors, pursuant to which we agreed to issue and sell in a registered direct offering, (i) an aggregate of 166,054 shares of our common stock, par value \$0.0001 per share at an offering price of \$7.05 per share, (ii) pre-funded warrants to purchase up to 70,827 shares of Common Stock, at a price per pre-funded warrant equal to \$7.0485, the price per share less \$0.0015, for gross proceeds of approximately \$1.7 million before the deduction of placement agent fees and offering expenses. The pre-funded warrants were subsequently exercised in full.

We also entered into an inducement agreement with certain warrant holders for the exercise of certain outstanding warrants to purchase up to an aggregate of 480,234 shares of our common stock originally issued in February 2024, having an exercise price of \$15.90 per share, at a reduced exercise price of \$7.05 per share, for gross proceeds of approximately \$3.4 million before the deduction of placement agent fees and offering expenses. We also agreed to amend certain existing warrants to purchase up to an aggregate of 133,334 shares of common stock that were previously issued in November 2023 and have an exercise price of \$23.5125 per share such that the amended warrants will have a reduced exercise price of \$7.05 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 SPA, we also agreed to issue and sell unregistered warrants to purchase up to 1,863,706 shares of common stock. The warrants have an exercise price of \$7.05 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.

We agreed to pay the placement agent a cash fee equal to 7% of the aggregate gross proceeds of the offerings or \$354,000. We also agreed to pay the placement agent \$100,950 for expenses. We also issued to the placement agent warrants to purchase up to 50,200 shares of common stock. These warrants have an exercise price equal to \$8.8125 per share and are exercisable for five years from the commencement of sales in the Offerings.

2024 February Warrant Inducement

In February 2024, we entered into an Inducement Letter with certain holders of existing warrants to purchase up to an aggregate of 240,120 shares of our 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 240,120 shares of Common Stock at a reduced exercise price of \$19.65 per share in consideration of our agreement to issue new unregistered Series A Warrants to purchase up to 240,120 shares of Common Stock and new unregistered Series B Warrants to purchase up to 240,120 shares of Common Stock. The Series A Warrants have an exercise price of \$15.90 per share and have a term equal to eighteen months from the date of issuance. The Series B Warrants have an exercise price of \$15.90 per share and will expire on May 12, 2028. The gross proceeds to us 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, we entered into a waiver related to the 2023 Notes' SPA it had entered into as of October 23, 2023. The SPA contained restrictions on our ability to undertake certain transactions, which included entering into the Inducement Letter. The Waiver permitted us 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.

We utilized an exclusive placement agent for the 2024 Warrant Inducement and incurred approximately \$0.3 million in legal fees and other closing costs. Additionally, we issued to the placement agent as compensation unregistered warrants to purchase up to 16,811 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 \$24.5625 per share of Common Stock (equal to 125% of the reduced exercise price per Existing Warrant).

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 a research and development MPAR Grant. In September 2019, we were awarded a second research and development OUD grant related to the development of our TAAP/MPAR® abuse deterrent technology. Grant funds are awarded annually through a Notice of Award which contains certain terms and conditions including, but not limited to, complying with the grant program legislation, regulation and policy requirements, complying with conditions on expenditures of funds with respect to other applicable statutory requirements such as the federal appropriations acts, periodic reporting requirements, and budget requirements.

Operating Expenses

Research and Development Expenses

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

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

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

We do not track our research and development expenses on a program-by-program basis. Our direct external research and development expenses consist primarily of external costs, such as fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct our research and development as well as 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 into license, acquisition and option agreements to acquire the rights to future product candidates.

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

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- establishing an appropriate safety and efficacy profile with investigational new drug (“IND”) enabling studies;
- successful patient enrollment in and the initiation and completion of clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates.

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

General and Administrative Expenses

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

We anticipate that our general and administrative expenses 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 liability classified warrants

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

Interest Expense

Interest expense consists of interest accrued on our financed directors' and officers' insurance, and interest from the 2023 Notes based on the stated interest rate. In addition, the 2023 Notes reflects 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.

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, 2025, and December 31, 2024, 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 2021 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.

The following table summarizes our results of operations for the three months ended September 30, 2025 and 2024.

Results of Operations

Comparison of the Three Months Ended September 30, 2025 and 2024:

	Three Months Ended September 30,		
	2025	2024	Change
Federal grants	\$ 493,104	\$ 3,418,853	\$ (2,925,749)
Operating expenses:			
Research and development	2,954,909	1,690,674	1,264,235
General and administrative	1,279,290	1,083,433	195,857
Total operating expenses	4,234,199	2,774,107	1,460,092
Income (loss) from operations	(3,741,095)	644,746	(4,385,841)
Other income (expense):			
Change in fair value of liability classified warrants	998	6,403	(5,405)
Interest expense	(6,369)	(4,063)	(2,306)
Other income and expense, net	17,338	14,683	2,655
Total other income (expenses), net	11,967	17,023	(5,056)
Net income (loss)	(3,729,128)	661,769	(4,390,897)
Net loss attributable to noncontrolling interests	-	-	-
Deemed dividend related to warrants down round provision	-	-	-
Net income (loss) attributable to common stockholders	\$ (3,729,128)	\$ 661,769	\$ (4,390,897)

Federal Grants

Revenue from federal grants totaled \$0.5 million for the three months ended September 30, 2025, compared to \$3.4 million for the three months ended September 30, 2024, respectively. This \$2.9 million decrease is primarily due to the timing of research activities eligible for funding under the MPAR grant which began in September 2024. The 2024 period included significant funding under the OUD grant with research activity following the selection of a lead product candidate in June 2024.

Research and Development Expenses

Research and development expenses were \$3.0 million for the three months ended September 30, 2025, compared to \$1.7 million for the three months ended September 30, 2024, representing an increase of \$1.3 million. The increase was primarily the result of external research and development costs related to increased clinical and pre-clinical activity for PF614 and PF614-MPAR in the 2025 period. We expect future research and development expenses to increase once we begin the Phase 3 clinical trial for PF614, with such timing dependent upon our ability to raise capital sufficient to fund these expenses.

General and Administrative Expenses

General and administrative expenses were \$1.3 million for the three months ended September 30, 2025 and \$1.1 million the three months ended September 30, 2024. 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, 2025, consisted primarily of interest income from cash and cash equivalents. The comparative period for 2024 consisted primarily of interest expense associated with the amortization of the original issue discount and the debt issuance costs for the 2023 Notes.

Results of Operations

Comparison of the nine months ended September 30, 2025 and 2024:

	Nine Months Ended September 30,		Change
	2025	2024	
Federal grants	\$ 3,184,314	\$ 3,906,372	\$ (722,058)
Operating expenses:			
Research and development	6,763,866	3,416,807	3,347,059
General and administrative	3,879,569	3,643,223	236,346
Total operating expenses	10,643,435	7,060,030	3,583,405
Loss from operations	(7,459,121)	(3,153,658)	(4,305,463)
Other income (expense):			
Change in fair value of liability classified warrants	10,061	23,175	(13,114)
Interest expense	(13,385)	(1,279,691)	1,266,306
Other income and expense, net	54,227	(12,413)	66,640
Total other income (expenses), net	50,903	(1,268,929)	1,319,832
Net loss	(7,408,218)	(4,422,587)	(2,985,631)
Net loss attributable to noncontrolling interests	(166)	(74)	(92)
Deemed dividend related to warrants down round provision	-	290	(290)
Net loss attributable to common stockholders	\$ (7,408,052)	\$ (4,422,803)	\$ (2,985,249)

Federal grant funding

Funding from federal grants for the nine months ended September 30, 2025 and 2024 totaled \$3.2 million and \$3.9 million, respectively. The decrease of approximately \$0.7 million is due to the timing of research activities eligible for funding under the OUD and MPAR grants. A decrease of \$2.1 million in funding under the OUD grant that ended in August 2024 was offset by an increase of \$1.4 million in funding under the MPAR grant which began in September 2024.

Research and development expenses

Research and development expenses for the nine months ended September 30, 2025, and 2024 were \$6.8 million and \$3.4 million, respectively, representing an increase of \$3.3 million. The increase was primarily the result of external research and development costs related to increased clinical and pre-clinical programs for PF614 and PF614-MPAR. We expect future research and development expenses to increase once we begin the Phase 3 clinical trial for PF614, with such timing dependent upon our ability to raise capital sufficient to fund these expenses.

General and administrative expenses

General and administrative expenses for the nine months ended September 30, 2025, and 2024 were \$3.9 million and \$3.6 million, respectively. We expect future general and administrative expenses to approximate current levels.

Other income and expense

Other income and expense for the nine months ended September 30, 2025, consisted primarily of interest income from cash and cash equivalents. 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 associated with the 2023 Notes.

Liquidity and Capital Resources

Sources of Liquidity and Capital

As of September 30, 2025, we had \$1.7 million of cash and cash equivalents. In November 2025, we completed a convertible preferred stock offering with gross proceeds of \$4 million. Since inception, we have generated limited revenues and have incurred significant operating losses and negative cash flows from our operations, and we anticipate that we will continue to incur losses for at least the foreseeable future. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all.

We have funded our operations to date primarily with proceeds from the sale of common equity, exercise of warrants for 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 funding under the MPAR federal research grant totaled \$8.7 million at September 30, 2025, 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 late first quarter of 2026, which raises substantial doubt about our ability to continue as a going concern.

Cash Flows for the nine months ended September 30, 2025, and 2024

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

	Nine Months Ended September 30,	
	2025	2024
Net cash used in operating activities	\$ (6,280,459)	\$ (6,738,610)
Net cash used in investing activities	(123,643)	-
Net cash provided by financing activities	4,575,243	9,768,598
Net increase (decrease) in cash and cash equivalents	\$ (1,828,859)	\$ 3,029,988

Operating Activities

During the nine months ended September 30, 2025 and 2024, we used cash in operating activities of \$6.3 million and \$6.7 million, respectively. The decrease primarily resulted from greater cash inflows from grant funding in 2025.

Financing Activities

During the nine months ended September 30, 2025, net cash provided by financing activities was \$4.6 million, primarily consisting of net proceeds from warrant inducements, a public offering of common stock and warrant exercises. During the nine months ended September 30, 2024, net cash provided by financing activities was \$9.8 million, primarily consisting of net proceeds from a public offering of common stock, warrant inducement and warrant exercises, and less repayment of convertible notes.

Funding Requirements

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

We expect our expenses, excluding non-cash expenses to recognize the fair value of warrants and convertible notes, to remain elevated 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, our 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, 2025, included an estimated \$7.3 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 as a result of many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs, timing and ability to manufacture our product candidates to supply our clinical and preclinical development efforts and our clinical trials;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade product and necessary inventory to support commercial launch;

- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, expanding and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Critical Accounting Policies and Significant Judgments and Estimates

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

While our significant accounting policies are described in more detail in Note 3 to our audited consolidated financial statements included in our 2024 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 period.

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our 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 Disclosure About Market Risk

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

Interest Rate Risk

Our cash and cash equivalents as of September 30, 2025, 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, 2025. 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, 2025. 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 2024 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.

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits.

The following exhibits are filed as part of this report:

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

* Filed herewith.

SIGNATURES

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

ENSYSCE BIOSCIENCES, INC.

Date: November 14, 2025

/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 14, 2025

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

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

I, David Humphrey, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ensysce Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2025

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

**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, 2025, 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 14, 2025

/s/ Lynn Kirkpatrick

Lynn Kirkpatrick
Chief Executive Officer
(Principal Executive Officer)

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

**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, 2025, 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 14, 2025

/s/ David Humphrey

David Humphrey
Chief Financial Officer
(Principal Financial Officer)

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