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

FORM S-3

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

ENSYSCE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

2834

(Primary Standard Industrial
Classification Code Number)

82-2755287

(I.R.S. Employer
Identification Number)

7946 Ivanhoe Avenue, Suite 201
La Jolla, California 92037
(858) 263-4196

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

Dr. Lynn Kirkpatrick
President, Chief Executive Officer & Director
7946 Ivanhoe Avenue, Suite 201
La Jolla, California 92037
(858) 263-4196

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: ☐

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. ☒

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

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

If this Form is a post-effective amendment filed pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ☐

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

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said section 8(a), may determine.

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

Subject to Completion. Dated April [], 2025.

PRELIMINARY PROSPECTUS



ENSYSCE BIOSCIENCES, INC.

Up to 652,439 Shares of Common Stock Underlying Series A-5 Warrants, Series A-6 Warrants and Placement Agent Warrants

This prospectus relates to the issuance by us and the resale by the selling security holders named in this prospectus (the “Selling Securityholders”) of up to an aggregate of 652,439 shares of our common stock, par value \$0.0001 per share (“common stock”), which consists of (i) up to 315,188 shares of common stock that are issuable to certain Selling Securityholders upon the exercise of Series A-5 Warrants to purchase shares of our common stock at a per share exercise price of \$3.24 that we issued to certain Selling Securityholders in the closing of a private placement that occurred on March 31, 2025 (the “Series A-5 Warrants”); (ii) up to 315,188 shares of common stock that are issuable to certain Selling Securityholders upon the exercise of Series A-6 Warrants to purchase shares of our common stock at a per share exercise price of \$3.24 that we issued to certain Selling Securityholders in a closing of a private placement that occurred on March 31, 2025 (the “Series A-6 Warrants”); and (iii) up to 22,063 shares of common stock that are issuable to certain Selling Securityholders upon the exercise of certain Placement Agent Warrants (the “Placement Agent Warrants,” and together with the Series A-5 Warrants and the Series A-6 Warrants, the “Investor Warrants”). See “Description of Capital Stock — Warrants — Investor Warrants” beginning on page 12 of this prospectus.

Our registration of the securities covered by this prospectus does not mean that either we or the Selling Securityholders will issue, offer or sell, as applicable, any of the securities being registered. The Selling Securityholders may offer, sell, or distribute all or a portion of the securities being registered publicly or through private transactions at prevailing market prices or at negotiated prices. We will not receive any of the proceeds from the sales of our common stock by the Selling Securityholders pursuant to this prospectus. We will, however, receive the net proceeds of any Investor Warrants if exercised for cash. We will bear all costs, expenses and fees in connection with the registration of these securities, including with regard to compliance with state securities or “blue sky” laws. The Selling Securityholders will bear all commissions and discounts, if any, attributable to their sale of shares of our common stock. See “Plan of Distribution” beginning on page 17 of this prospectus.

Our common stock is listed on The Nasdaq Capital Market under the symbol “ENSC” and certain warrants we previously issued (the “Public Warrants”) are quoted on the OTC Pink Open Market under the symbol “ENSCW.” On April 11, 2025, the last reported sale price of our common stock on The Nasdaq Capital Market was \$2.03 per share and the closing bid price for our Public Warrants as quoted on the OTC Pink Open Market was \$0.013.

You should read this prospectus and any prospectus supplement or amendment carefully before you invest in our securities.

Our business and investing in our securities involve a high degree of risk. See “Risk Factors” beginning on page 7 of this prospectus.

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

Prospectus dated [], 2025.

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GLOSSARY

Definitions:

2013 Framework	Financial reporting criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013)
2021 Omnibus Incentive Plan	Ensysce Biosciences, Inc. Amended and Restated 2021 Omnibus Incentive Plan
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
2024 August Offering	The Company's August 2024 registered direct offering of common stock, issuance of private placement warrants and the cash exercise of certain existing warrants at a reduced price and the issuance of new warrants
ADFs	Abuse deterrent formulations
ADHD	Attention deficit hyperactivity disorder
ANDA	Abbreviated New Drug Application
API	Active pharmaceutical ingredient
AUC	Area under the concentration time curve
Board	Board of directors of Ensysce, or a committee thereof, as applicable
Business Combination	The definitive merger agreement among LACQ, Merger Sub and Former Ensysce, dated January 31, 2021, providing for, among other things, and subject to terms and conditions therein, the business combination between LACQ and Former Ensysce pursuant to the merger of Merger Sub with and into Former Ensysce, with Former Ensysce continuing as the surviving entity and as a wholly-owned subsidiary of LACQ
CARA	Comprehensive Addiction and Recovery Act
CDC	Center for Disease Control
CDER	Center for Drug Evaluation and Research
cGMP	Current Good Manufacturing Practice
Cmax	Maximum plasma concentration
CMC	Chemistry, manufacturing, and controls
CMOs	Contract manufacturing organizations

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Definitions:

CNS	Central nervous system
Company	Ensysce Biosciences, Inc. and its consolidated subsidiaries
COVID-19	Novel coronavirus disease
Covistat	A subsidiary renamed EBIR, Inc.
CROs	Contract research organizations
CSA	Controlled Substances Act
CSOS	Controlled Substance Ordering System
DEA	United States Drug Enforcement Agency
DSCSA	Title II of the Federal Drug Quality and Security Act of 2013, known as the Drug Supply Chain Security Act
EB	Ensysce Biosciences, Inc. prior to its merger with Signature Acquisition Corp. pursuant to the EB-ST Agreement.
EBIR	Previously known as Covistat, Inc., EBIR, Inc. is a clinical stage pharmaceutical company that is developing a compound utilized in the Company's overdose protection program for the treatment of COVID-19 and 79.2%-owned subsidiary of the Company
EB-ST Agreement	Agreement and Plan of Merger, dated as of December 28, 2015, by and among Signature, SAQ, and EB
EMA	European Medicines Agency
Ensysce	Ensysce Biosciences Inc.
EPO	European Patent Office
ETASU	Elements to assure a products safe use
Exchange Act	Securities Exchange Act of 1934, as amended
FDA	United States Food and Drug Administration

FDC Act	Federal Food, Drug and Cosmetic Act, as amended
Former Ensysce	Ensysce Biosciences, Inc., a Delaware corporation, prior to the consummation of the merger with and into Merger Sub
GAAP	Generally Accepted Accounting Principles in the United States of America
GCP	Good Clinical Practices
GMP	Good Manufacturing Practices
Hatch-Waxman Act or Hatch-Waxman Amendments	Drug Price Competition and Patent Term Restoration Act of 1984
HHS	United States Department of Health and Human Services
IMPDs	Investigational Medicinal Product Dossiers
IND	Investigational New Drug
IRB	Institutional Review Board

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Definitions:

JOBS Act	Jumpstart Our Business Startups Act of 2012
LACQ	Leisure Acquisition Corp., a Delaware Corporation
LACQ Warrants	Warrants that relate to the Business Combination or were issued prior to it and are exercisable for 1,469 shares of our common stock at a weighted average exercise price of \$40,889.04 per share
MAD	Multi-Ascending Dose
March 2025 SPA	The Securities Purchase Agreement, dated as of March 30, 2025, by and between Ensysce and the institutional investors party thereto
March 2025 Registered Direct Offering	March 2025 registered direct offering of common stock (239,594 shares and pre-funded warrants to purchase 75,594 shares), private placement warrants (to purchase up to 22,063 shares) and the issuance of new warrants (to purchase up to 630,376 shares)
Merger	The merger of Merger Sub with and into Former Ensysce, with Former Ensysce continuing as the surviving entity and a wholly owned subsidiary of LACQ, which changed its name to Ensysce Biosciences, Inc. following consummation of the Merger.
Merger Agreement	Agreement and Plan of Merger, dated as of January 31, 2021, by and among LACQ, Merger Sub and Former Ensysce, providing for, among other things, and subject to the terms and conditions therein, a business combination between Former Ensysce and LACQ pursuant to the proposed merger of Merger Sub with and into Former Ensysce, with Former Ensysce surviving the transaction as a wholly-owned subsidiary of LACQ, which changed its name to Ensysce Biosciences, Inc. following consummation of the Merger
Merger Sub	EB Merger Sub, Inc., a Delaware corporation, a wholly-owned subsidiary of LACQ prior to the consummation of the Merger
MPAR Grant	Research and development grant related to the development of its MPAR [®] overdose prevention technology awarded to the Company by NIH through NIDA in September 2018
Nasdaq	The Nasdaq Stock Market LLC
NCE	New Chemical Entity
NDA	New Drug Application
NEO	Named Executive Officer
NIDA	National Institute of Drug Abuse
NIH	National Institutes of Health
NME	New molecular entity
Orange Book	FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations
OD 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

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Definitions:

PCT	Patent Cooperation Treaty
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PDMA	U.S. Prescription Drug Marketing Act
PK	Pharmacokinetics
PTA	Patent Term Adjustment
PTE	Patent Term Extension
Public Warrants	The redeemable warrants issued by us and sold as part of the units in the LACQ IPO (whether they were purchased in the LACQ IPO or thereafter in the open market). The Public Warrants are exercisable for an aggregate of approximately 2,778 shares of our common stock at an exercise price of \$41,400.00 per share
R&D	Research and Development
Recro	Recro Gainesville LLC
Recro Agreement	Manufacturing Agreement, dated September 19, 2019, by and between Recro Gainesville LLC and the Company
REMS	Risk evaluation and mitigation strategy
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SAQ	Signature Acquisition Corp., a wholly-owned subsidiary of Signature
SEC	U.S. Securities and Exchange Commission
Securities Act	Securities Act of 1933, as amended
Signature	Signature Therapeutics Inc.
SPA	A Securities Purchase Agreement, dated as of September 24, 2021, June 30, 2022, October 23, 2023, or August 28, 2024 as the context dictates, by and between Ensysce and the institutional investors party thereto
SUPPORT Act	Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act
TAAP	Trypsin Activated Abuse Protection
TEAEs	Treatment-emergent adverse events
USPTO	United States Patent and Trademark Office

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ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information other than the information that we have provided or incorporated by reference in this prospectus and your reliance on any unauthorized information or representation is at your own risk. This prospectus may be used only in jurisdictions where offers and sales of these securities are permitted. You should assume that the information contained in this prospectus is accurate only as of the date of this prospectus, and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or of any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since those dates. This prospectus contains market data and industry statistics and forecasts that are based on independent industry publications and other publicly available information. Although we believe these sources are reliable, we do not guarantee the accuracy or completeness of this information and we have not independently verified this information. In addition, the market and industry data and forecasts that may be included in this prospectus may involve estimates, assumptions and other risks and uncertainties and are subject to change based on various factors, including those discussed under the heading “*Risk Factors*” contained in this prospectus. Accordingly, investors should not place undue reliance on this information.

The representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

To the extent there is a conflict between the information contained in this prospectus, on the one hand, and the information contained in any document incorporated by reference filed with the U.S. Securities and Exchange Commission (the “SEC”) before the date of this prospectus, on the other hand, you should rely on the information in this prospectus. If any statement in a document incorporated by reference is inconsistent with a statement in another document incorporated by reference having a later date, the statement in the document having the later date modifies or supersedes the earlier statement.

Neither we nor the Selling Securityholders has authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus, any post-effective amendment, or any applicable prospectus supplement prepared by or on behalf of us or to which we have referred you. We and the Selling Securityholders take no responsibility for and can provide no assurance as to the reliability of, any other information that others may give you. Neither we, nor the Selling Securityholders, will make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus, any post-effective amendment and any applicable prospectus supplement to this prospectus is accurate only as of the date on its respective cover.

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

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

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes statements that express our opinions, expectations, beliefs, plans, objectives, assumptions, or projections regarding future events or future results and therefore are, or may be deemed to be, “forward-looking statements.” These forward-looking statements can generally be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “seeks,” “projects,” “intends,” “plans,” “may,” “will,” or “should” or, in each case, their negative or other variations or comparable terminology. These forward-looking statements include all matters that are not historical facts. They appear in several places throughout this registration statement/prospectus and include statements regarding our intentions, beliefs or current expectations concerning, among other things, results of operations, financial condition, liquidity, prospects, growth, strategies and the markets in which we operate. Such forward-looking statements are based on available current market material and management’s expectations, beliefs and forecasts concerning future events impacting our company. Factors that may impact such forward-looking statements include:

- our estimates regarding expenses, revenue, capital requirements and timing and availability of and the need for additional financing will almost certainly not match actual amounts and timing;
- our ability to continue as a going concern for the next twelve months;
- the risk that our lead product candidate PF614 and PF614-MPAR may not be successful in limiting or impeding abuse, overdose, or misuse or providing additional safety upon commercialization;
- 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 the Annual Report on Form 10-K for the year ended December 31, 2024;
- 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 establish and maintain effective internal controls over financial reporting;
- the risk that our common stock will be delisted from Nasdaq;
- the risk that we may not be able to regain or maintain compliance with applicable listing standards of Nasdaq;
- potential litigation associated with the Business Combination Transactions;
- other factors disclosed in the Annual Report on Form 10-K for the year ended December 31, 2024; and
- other factors beyond our control.

The forward-looking statements contained in this prospectus are based on our current expectations and beliefs concerning future developments and their potential effects on our company. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve risks, uncertainties or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading “Risk Factors” in this prospectus. Should one or more of these risks or uncertainties materialize, or should any of the assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We will not undertake any obligation to update or revise any forward-looking statements, whether because of new information, future events or otherwise,

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described under “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, and any subsequent Quarterly Report on Form 10-Q and our other filings with the SEC, all of which are incorporated by reference, together with the Risk Factors set forth below, before making an investment decision. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have an adverse effect on our business, cash flows, financial condition and results of operations. You should also carefully consider the following risk factors in addition to the other information included in this registration statement/prospectus, including matters addressed in the section entitled “Cautionary Note Regarding Forward-Looking Statements.” We may face additional risks and uncertainties that are not presently known to us or that we currently deem immaterial, which may also impair our business or financial condition.

Risks Related to this Offering and Our Securities

We need to raise additional capital after this offering to support our operations.

We will not receive any of the proceeds from the sales of our common stock by the Selling Securityholders pursuant to this prospectus.

We have incurred substantial losses since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect to continue to incur significant losses for the foreseeable future as we continue our research and development of, and seek regulatory approvals for, our product candidates.

Our current cash on hand is sufficient to fund operations into the third quarter of 2025. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2024 and 2023 contains explanatory language that substantial doubt exists about our ability to continue as a going concern. We have reduced expenses because we do not have access to sufficient cash and liquidity to finance our business operations as currently contemplated and may be compelled to reduce further general and administrative expenses and delay research and development projects until we are able to obtain sufficient financing. We may find it difficult to raise money on terms favorable to us or at all. The failure to obtain sufficient capital to support our operations would have a material adverse effect on our business, financial condition and results of operations. If sufficient financing is not received timely, we would then need to pursue a plan to license or sell assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

If we are unable to maintain compliance with the listing standards of Nasdaq, our common stock could be delisted and may become subject to “penny stock” rules, which could have a material adverse effect on the liquidity of our common stock, the ability of investors to sell their shares and our ability to raise funding.

On November 14, 2024, we received notice from Nasdaq stating that we had demonstrated compliance with the \$2.5 million stockholders' equity requirement set forth in Nasdaq Listing Rule 5550(b)(1) as of September 30, 2024. On December 20, 2024, we received notice from Nasdaq that we had regained compliance with the bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2). There can be no assurance that we will be able to maintain compliance with such Nasdaq Listing Rules and our common stock could be delisted.

The de-listing of our common stock on Nasdaq could have a material adverse effect on us, including on our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. Upon any delisting, our common stock could become subject to the regulations of the SEC relating to the market for penny stocks. Penny stocks are securities with a price of less than \$5.00 per share unless (i) the securities are traded on a “recognized” national exchange or (ii) the issuer has net tangible assets less than \$2,000,000 (if the issuer has been in continuous operation for at least three years) or \$5,000,000 (if in continuous operation for less than three years), or with average annual revenues of less than \$6,000,000 for the last three years.

The procedures applicable to penny stocks requires a broker-dealer to (i) obtain from the investor information concerning his financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of stockholders to sell their common stock in the secondary market.

If you purchase our securities in this offering you may experience future dilution as a result of future equity offerings or other equity issuances.

To raise additional capital, we will need to offer and issue additional shares of our common stock or other securities convertible into or exchangeable for our common stock in the future. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share in this offering.

We have a significant number of warrants and stock options outstanding. Further, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

The market price of our common stock and the trading volume of our common stock has been and may continue to be highly volatile, and such volatility could cause the market price of our common stock to decrease.

Between January 1, 2025, and April 11, 2025, the market price of our common stock fluctuated from a low of \$1.70 per share to a high of \$9.57 per share, and our stock price continues to fluctuate. The market price and trading volume of our common stock may continue to fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- our ability to grow our revenue and customer base;
- The announcement or the market introduction of new products or product enhancements by us or our competitors;
- the trading volume of our common stock;
- developments concerning regulatory oversight and approvals;

- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;
- successes or challenges in our collaborative arrangements or alternative funding sources;
- developments in the health care and life science industries;
- the results of product liability or intellectual property lawsuits;
- adverse effects on our business condition and results of operations from general economic and market conditions and overall fluctuations in the United States and international markets, including deteriorating market conditions due to investor concerns regarding inflation and Russia's war on Ukraine;
- future issuances of common stock or other securities;
- the addition or departure of key personnel;
- announcements by us or our competitors of acquisitions, investments or strategic alliances; and
- general market conditions and other factors, including factors unrelated to our operating performance.

Further, the stock market in general and micro-cap clinical trial pharmaceutical issuers in particular, have recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock and the loss of some or all your investment.

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USE OF PROCEEDS

The Selling Securityholders will receive all the proceeds from this offering. We will, however, receive the net proceeds of any Investor Warrants if exercised for cash. Proceeds, if any, received from the exercise of such Investor Warrants will be used for working capital for general corporate purposes. No assurances can be given that any of such Investor Warrants will be exercised. The Selling Securityholders will pay any underwriting discounts and commissions and expenses incurred by the Selling Securityholders for brokerage, accounting, tax or legal services or any other expenses incurred by the Selling Securityholders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including all registration and filing fees, and fees and expenses for our counsel and our independent registered public accountants.

DESCRIPTION OF CAPITAL STOCK

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

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

Common Stock

As of April 11, 2025, 1,644,728 shares of our common stock were issued and outstanding.

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

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

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

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

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Classified Board

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

Authorized but Unissued Shares

Our authorized but unissued shares of common and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. However, the listing requirements of the Nasdaq, which apply if and so long as our common stock remains listed on the Nasdaq, require stockholder approval of certain issuances equal to or exceeding 20% of the then outstanding voting

power or then outstanding number of shares of common stock. Additional shares that may be used in the future may be issued for a variety of corporate purposes, including future public offerings, to raise additional capital, or to facilitate acquisitions. The existence of authorized but unissued and unreserved common stock and preferred stock could render it more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Special Meetings of Stockholders

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

Advance Notice Requirements for Stockholder Proposals and Director Nominations

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

Amendment of Charter or Bylaws

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

Exclusive Forum

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

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders;

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- any action asserting a claim against us arising pursuant to any provision of the DGCL, our charter or our bylaws (as either may be amended, restated, modified, supplemented or waived from time to time);
- any action to interpret, apply, enforce or determine the validity of our charter or our bylaws; and
- any action asserting a claim against us governed by the internal affairs doctrine.

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

Delaware Anti-Takeover Statute

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

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

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

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

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Warrants

Investor Warrants

2025 Registered Direct Offering and 2025 Private Purchase of Warrants

On March 30, 2025, we entered into a Securities Purchase Agreement (the “*March 2025 SPA*”) with certain institutional investors, pursuant to which we agreed to issue and sell in a registered direct offering (the “*March 2025 Registered Direct Offering*”), (i) an aggregate of 239,594 shares of our common stock, par value \$0.0001 per share at an offering price of \$3.49 per share and (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.

In a concurrent private placement, pursuant to the terms of the March 2025 SPA, we also agreed to issue and sell unregistered Series A-5 Warrants to purchase up to 315,188 shares of our common stock, and Series A-6 Warrants to purchase up to 315,188 shares of our common stock. Each of the Series A-5 Warrants and Series A-6 Warrants are immediately exercisable for one share of our common stock at an exercise price of \$3.24 per share. The Series A-6 Warrants have a term of five years from the date of issuance and the Series A-5 Warrants have a term of eighteen months from the date of issuance. The warrants contain customary anti-dilution adjustments to the exercise price, including for share splits, share dividends, rights offering and pro rata distributions.

In connection with the March 2025 SPA and the March 2025 Registered Direct Offering, we issued to a placement agent unregistered warrants to purchase up to 22,063 shares of common stock (the “*Placement Agent Warrants*”). The Placement Agent Warrants expire on March 30, 2030, and have an exercise price of \$4.3625 per share of common stock (equal to 125% of the issue price per share of \$3.49 of shares issued in the March 2025 Registered Direct Offering). We have filed a registration statement, of which this prospectus is a part, providing for the resale of the shares of common stock issuable upon exercise of the Series A-5 Warrants, Series A-6 Warrants and Placement Agent Warrants.

Certain Prior Warrants and Notes

2024 Registered Direct Offering and 2024 August Warrant Inducement

In August 2024, we entered into a definitive Securities Purchase Agreement 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 \$0.0001, 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 Securities Purchase Agreement, 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.

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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).

2023 Notes

On October 23, 2023, we entered into a Securities Purchase Agreement (the “SPA”) for an aggregate financing of \$1.7 million with investors, including \$0.2 million with a board member. At the first closing under the SPA, which occurred on October 25, 2023, we 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 our common stock in the aggregate. At the second closing under the SPA, which occurred on November 28, 2023, we 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 notes matured on April 25, 2024 and May 28, 2024, respectively.

The combined notes are subject to an original issue discount of 8%, have a term of six months from their respective date of issuance and accrue interest at the rate of 6.0% per annum. The notes are convertible into common stock, at a per share conversion price equal to \$23.51. Beginning ninety days following issuance of the notes at the first closing and second closing, respectively, we are obligated to redeem monthly one third of the original principal amount under the applicable note, plus accrued but unpaid

interest, liquidated damages and any other amounts then owing to the holder of such note. We are required to pay the redemption amount in cash with a premium of 10% or, at the election of the investor at any time, some or all of the principal amount and interest may be paid by conversion of shares under the note into common stock based on a conversion price equal to \$23.51. Conversions and repayments of principal and interest on the notes in January and February 2024 totaled \$1.7 million.

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The warrants have an exercise price of \$23.51 and are exercisable for five years following issuance on each of the first and second closing dates under the SPA. Warrants for 88,261 shares of common stock were exercised in January 2024.

2023 May Offering

On May 12, 2023, we completed a public offering of an aggregate of 120,059 shares of its common stock at par value \$0.0001 per share (including pre-funded warrants in lieu thereof), Series A-1 warrants to purchase up to 120,059 shares of common stock and Series A-2 warrants to purchase up to 120,059 shares of common stock, at a combined public offering price of \$58.31 per share (or pre-funded warrant in lieu thereof) and accompanying warrants. The Series A-1 warrants have an exercise price of \$54.60 per share, are exercisable immediately upon issuance and expire five years from the date of issuance, and the Series A-2 warrants have an exercise price of \$54.60 per share, are exercisable immediately upon issuance and expire eighteen months from the date of issuance. A holder of a warrant issued in the offering will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or 9.99% at the election of the holder prior to the date of issuance) of the number of shares of Common Stock outstanding immediately after giving effect to such exercise; provided, however, that upon 61 days' prior notice us, the holder may increase or decrease the beneficial ownership limitation, provided that in no event shall the beneficial ownership limitation exceed 9.99%. Gross proceeds from this offering are approximately \$7.0 million before the deduction of placement agent fees and related costs of \$0.7 million. The Series A-1 and Series A-2 warrants were repriced to \$19.65 per share and exercised in February 2024.

H.C. Wainwright & Co. acted as the exclusive placement agent for the offering. We also registered warrants issued to the placement agent to purchase 8,404 shares of common stock at a per share exercise price of \$72.882, which is 125% of the price of the shares in the offering.

In connection with the offering, we amended certain existing warrants to purchase up to an aggregate of 14,006 shares of our common stock that were previously issued in September 2021 through December 2022 to purchasers in the offering at exercise prices ranging from \$252.00 to \$2,808.00 per share, such that the amended warrants have a reduced exercise price of \$54.60 per share, at an additional offering price of \$1.875 per amended warrant.

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SELLING SECURITYHOLDERS

This prospectus relates to the resale by the Selling Securityholders from time to time of up to 652,439 shares of our common stock underlying the Investor Warrants. The Selling Securityholders may offer and sell some, all or none of the common stock set forth below pursuant to this prospectus and any accompanying prospectus supplement. As used in this prospectus, the term "Selling Securityholders" includes the persons listed in the table below, together with any additional selling securityholders listed in a subsequent amendment to this prospectus, and their pledgees, donees, transferees, assignees, successors, designees and others who later come to hold any of the Selling Securityholders' interests in the common stock, other than through a public sale.

The table below lists the Selling Securityholders and provides information about the beneficial ownership of the shares of common stock held by each Selling Securityholder on or about April 11, 2025. The second column lists the number of shares of common stock owned by each Selling Securityholder, based on exercise of the Investor Warrants and other warrants held by each selling securityholder, without regard to any limitations on exercises contained therein. The third column lists the shares of common stock being offered by this prospectus by the Selling Securityholders. This prospectus generally covers the resale of the maximum number of shares of common stock issuable upon exercise of the Investor Warrants, determined as if the Investor Warrants had been exercised in full, in each case without regard to any limitations on the exercise of the Investor Warrants. The fourth column assumes the sale of all shares offered by the Selling Securityholders by this prospectus. In the fifth column, the applicable percentage ownership of common stock beneficially owned is based on approximately 1,644,728 shares of common stock outstanding as of April 11, 2025, accounting for any limitations on the exercise of warrants contained therein.

We have determined beneficial ownership in accordance with the rules of the SEC and beneficial ownership includes voting or investment power over securities. We have prepared the table based on information given to us by, or on behalf of, the Selling Securityholders.

Please see the section titled "Plan of Distribution" in this prospectus for further information regarding the Selling Securityholders' methods of distributing these shares.

Name	Shares Owned Prior to Offering	Shares Underlying Investor Warrants Registered for Sale Hereby	Shares Owned After Offering	Percent Beneficially Owned After Offering
3i, LP (1)	835,687	315,188	520,499	4.99%
Nomis Bay Ltd (2)	278,520	201,720	76,800	4.7%
BPY Limited (3)	156,668	113,468	43,200	2.6%
Michael Vasinkevich (4)	63,395	14,148	49,247	3.0%
James Cappuccio (4)	18,785	4,192	14,593	*
Noam Rubinstein (4)	12,359	2,758	9,601	*
Craig Schwabe (4)	3,336	744	2,592	*
Charles Worthman (4)	989	221	768	*

* Less than 1%

- (1) Consists of (i) 315,188 shares of common stock issuable upon the exercise of Series A-5 Warrants and Series A-6 Warrants to purchase shares of common stock that were issued to the Selling Securityholder pursuant to the March 2025 SPA, which warrants are subject to, as applicable, certain beneficial ownership limitations, which provide that a holder of such warrants will not have the right to exercise any portion thereof if such holder, together with its affiliates, would beneficially own in excess of 4.99%, of the number of shares of common stock outstanding immediately after giving effect to such exercise, provided that such holder may, upon at least 61 days' prior notice to us, increase such limitation up to a maximum of 9.99% of the number of shares of common stock outstanding, (ii) 75,594 shares of common stock issuable upon the exercise of pre-funded warrants (the "Pre-funded Warrants"), at a remaining unpaid exercise price per Pre-funded Warrant equal to \$0.0001 and (iii) 444,905 shares of common stock issuable upon the exercise of warrants previously issued through time to the Selling Securityholder, which warrants are subject to certain beneficial ownership limitations, which provide that a holder of such warrants will not have the right to exercise any portion thereof if such holder, together with its affiliates, would beneficially own in excess of 4.99% or 9.99%, as elected by the Selling Securityholder with respect to the specific warrants, of the number of shares of common stock outstanding immediately after giving effect to such exercise, provided that such holder may increase such 4.99% limitation to a maximum of 9.99% or decrease such 9.99% limitation to 4.99% of the number of shares of common stock outstanding upon at least 61 days' prior notice to us. The maximum number of shares to be sold includes all shares of common stock issuable upon exercise of warrants without giving effect to such beneficial ownership limitation. The business address of 3i, LP is 2 Wooster Street, 2nd Floor, New York, NY 10013. Maier Joshua Tarlow is the manager of 3i Management, LLC, the general partner of 3i, LP, and has sole voting control and investment discretion over securities beneficially owned directly or indirectly by 3i Management, LLC and 3i, LP. Mr. Tarlow disclaims any beneficial ownership of the securities beneficially owned directly by 3i, LP and indirectly by 3i Management, LLC.

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- (2) Consists of (i) 201,720 shares of common stock issuable upon the exercise of Series A-5 Warrants and Series A-6 Warrants to purchase shares of common stock that were issued to the Selling Securityholder pursuant to the March 2025 SPA, which warrants are subject to, as applicable, certain beneficial ownership limitations, which provide that a holder of such warrants will not have the right to exercise any portion thereof if such holder, together with its affiliates, would beneficially own in excess of 4.99%, of the number of shares of common stock outstanding immediately after giving effect to such exercise, provided that such holder may decrease such limitation and further provided that upon at least 61 days' prior notice to us, such holder may increase such limitation up to a maximum of 9.99% of the number of shares of common stock outstanding and (ii) 76,800 shares of common stock. The maximum number of shares to be sold includes all shares of common stock issuable upon exercise of warrants without giving effect to such beneficial ownership limitation. The business address of Nomis Bay Ltd is 5 Reid Street, Hamilton, Bermuda HM 11. James Keyes has voting control and investment discretion over securities beneficially owned directly or indirectly by Nomis Bay Ltd. Mr. Keyes disclaims any beneficial ownership of the securities beneficially owned directly or indirectly by Nomis Bay Ltd.
- (3) Consists of (i) 113,468 shares of common stock issuable upon the exercise of Series A-5 Warrants and Series A-6 Warrants to purchase shares of common stock that were issued to the Selling Securityholder pursuant to the March 2025 SPA, which warrants are subject to, as applicable, certain beneficial ownership limitations, which provide that a holder of such warrants will not have the right to exercise any portion thereof if such holder, together with its affiliates, would beneficially own in excess of 4.99%, of the number of shares of common stock outstanding immediately after giving effect to such exercise, provided that such holder may decrease such limitation and further provided that upon at least 61 days' prior notice to us, such holder may increase such limitation up to a maximum of 9.99% of the number of shares of common stock outstanding and (ii) 43,200 shares of common stock. The business address of BPY Limited is 5 Reid Street, Hamilton, Bermuda HM 11. James Keyes has voting control and investment discretion over securities beneficially owned directly or indirectly by BPY Limited. Mr. Keyes disclaims any beneficial ownership of the securities beneficially owned directly or indirectly by BPY Limited.
- (4) Each of the Selling Securityholders is affiliated with H.C. Wainwright & Co., LLC, a registered broker dealer and has a registered address of c/o H.C. Wainwright & Co., LLC, 430 Park Ave, 3rd Floor, New York, NY 10022, and has sole voting and dispositive power over the securities held. The number of shares beneficially owned consists of shares of common stock issuable upon exercise of placement agent warrants, which were received as compensation. The Selling Securityholder acquired the placement agent warrants in the ordinary course of business and, at the time the placement agent warrants were acquired, the Selling Stockholder had no agreement or understanding, directly or indirectly, with any person to distribute such securities.

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PLAN OF DISTRIBUTION

Each Selling Securityholder, and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their Company securities covered hereby on the Nasdaq Capital Market or any other stock exchange, market or trading facility on which such securities are traded or in private transactions. These sales may be at fixed or negotiated prices.

A Selling Securityholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker dealer solicits purchasers;
- block trades in which the broker dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker dealer as principal and resale by the broker dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered after the effective date of the registration statement of which this prospectus is a part;
- in transactions through broker dealers that agree with the Selling Securityholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Securityholders may also sell securities under Rule 144 under the Securities Act, if available, rather than under this prospectus.

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Broker dealers engaged by the Selling Securityholders may arrange for other brokers dealers to participate in sales. Broker dealers may receive commissions or

discounts from the Selling Securityholders (or, if any broker dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the Selling Securityholders may enter hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities while hedging the positions they assume. The Selling Securityholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Securityholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Securityholders and any broker-dealers or agents that participate in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Securityholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities.

Because Selling Securityholders may be deemed to be “underwriters” within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. The Selling Securityholders have advised us that there is no underwriter or coordinating broker acting in connection with the proposed sale of the common stock (“*resale securities*”) by the Selling Securityholders.

We agreed to keep this prospectus effective for the Selling Securityholders for common stock resold following exercise of the Investor Warrants (the “*resale securities*”) at all times until no holder of the Investor Warrants holds any Investor Warrants or resale securities or certain other requirements are met. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Securityholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of securities of the common stock by the Selling Securityholders or any other person. We will make copies of this prospectus available to the Selling Securityholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

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LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by Troutman Pepper Locke LLP. Any underwriters or agents will be advised about other issues relating to the offering by counsel to be named in the applicable prospectus supplement.

EXPERTS

Our consolidated financial statements as of December 31, 2024 and 2023, and for the years ended, appearing in our Annual Report on Form 10-K for the year ended December 31, 2024, incorporated in this prospectus by reference, have been audited by Moss Adams LLP, an independent registered public accounting firm, as stated in their report (which report expresses an unqualified opinion and includes an explanatory paragraph regarding the existence of substantial doubt about the Company’s ability to continue as a going concern). Such consolidated financial statements are incorporated by reference in reliance upon the report of such firm given their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of the registration statement on Form S-3 filed with the SEC under the Securities Act and does not contain all the information set forth in the registration statement. Whenever a reference is made in this prospectus to any of our contracts, agreements or other documents, the reference may not be complete and you should refer to the exhibits that are a part of the registration statement or the exhibits to the reports or other documents incorporated herein by reference for a copy of such contract, agreement or other document.

We are currently subject to the reporting requirements of the Exchange Act, and in accordance therewith file periodic reports, proxy statements and other information with the SEC. Our SEC filings are available to you on the SEC’s website at <http://www.sec.gov> and in the “Investors” section of our website at www.ensysce.com. Our website and the information contained on that site, or connected to that site, are not incorporated into and are not a part of this prospectus.

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DOCUMENTS INCORPORATED BY REFERENCE

The SEC allows us to “incorporate by reference” information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus, while information that we file later with the SEC will automatically update and supersede the information in this prospectus. We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC:

- Our Annual Report on [Form 10-K](#) for the year ended December 31, 2024 filed with the SEC on March 10, 2025;
- Our Current Reports on Form 8-K filed with the SEC on [February 4, 2025](#), [March 10, 2025](#), [March 31, 2025](#) and [April 1, 2025](#) (in each case other than any portions thereof deemed furnished and not filed);
- All other reports filed with the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act, since the end of the fiscal year covered by the Annual Report on Form 10-K referenced above; and

- The [Form 8-A](#) filed with the SEC on November 28, 2017 by our predecessor corporation, Leisure Acquisition Corp., included a description of common stock that was updated with the filing of our: (i) Third Amended and Restated Certificate of Incorporation as [Exhibit 3.1](#) to our Current Report on Form 8-K, which was filed with the SEC on July 7, 2021 and (ii) Certificate of Amendment to Third Amended and Restated Certificate of Incorporation that was filed as Exhibit 3.1(b) to our Registration Statement on Form S-1 (File No. 333-268038), which was filed with the SEC on October 28, 2022.

We also incorporate by reference any future filings (other than any filings or portions of such reports that are not deemed “filed” under the Exchange Act in accordance with the Exchange Act and applicable SEC rules, including current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits furnished on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including those made after the date of the initial filing of the registration statement of which this prospectus is a part and prior to the effectiveness of the registration statement, until we file a post-effective amendment that indicates the termination of the offering of the securities made by this prospectus and will become a part of this prospectus from the date that such documents are filed with the SEC. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

We will furnish without charge to you, upon written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents by writing or telephoning us at the following address or phone number. Ensysce Biosciences, Inc., 7946 Ivanhoe Avenue, Suite 201, La Jolla, California 92037, telephone number (858) 263-4196. You may also access this information on our website at www.ensysce.com by viewing the “SEC Filings” subsection of the “Investors” menu. No additional information is deemed to be part of or incorporated by reference into this prospectus.

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Up to 652,439 Shares of Common Stock Underlying Series A-5 Warrants, Series A-6 Warrants and Placement Agent Warrants



ENSYSCE BIOSCIENCES, INC.

PROSPECTUS

[], 2025

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

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

SEC registration fee	\$	187
Accounting fees and expenses		15,000
Legal fees and expenses		15,000
Miscellaneous		5,000
Total	\$	35,187

Item 15. Indemnification of Directors and Officers.

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

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

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

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

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

The indemnification rights set forth above shall not be exclusive of any other right which an indemnified person may have or hereafter acquire under any statute, any provision of the registrant's third amended and restated certificate of incorporation, the registrant's amended and restated bylaws, agreement, vote of stockholders or disinterested directors or otherwise. Notwithstanding the foregoing, the registrant shall not be obligated to indemnify a director or officer in respect of a proceeding (or part thereof) instituted by such director or officer, unless such proceeding (or part thereof) has been authorized by the board of directors pursuant to the applicable procedure outlined in the registrant's amended and restated bylaws.

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

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

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

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

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Index

No.	Description of Exhibit
2.1†	<u>Agreement and Plan of Merger, dated January 31, 2021, by and among Leisure Acquisition Corp., Ensysce Biosciences, Inc. and EB Merger Sub, Inc. (incorporated by reference to Exhibit 2.1 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).</u>
4.1	<u>Warrant Agreement, dated December 1, 2017, between the Leisure Acquisition Corp. and Continental Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.1 filed with the registrant's Current Report on Form 8-K (File No. 001-38306) on December 5, 2017).</u>
4.2	<u>Investor Rights Agreement between Ensysce Biosciences, Inc. and the Investors listed on the signature pages thereto dated as of May 11, 2018 (incorporated by reference to Exhibit 4.6 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).</u>
4.3	<u>Form of Warrant Certificate issued to previous holders of Private Placement Warrants and other private warrants (incorporated by reference to Exhibit 4.8 filed with the registrant's Registration Statement on Form S-4 (File No.333-254279) initially filed on March 15, 2021).</u>
4.4	<u>Form of Common Stock Purchase Warrant to be issued by the Company pursuant to and in accordance with the Securities Purchase Agreement (incorporated by reference to Exhibit 4.7 filed with the registrant's Current Report on Form 8-K (File No. 001-38306) initially filed on September 27, 2021).</u>
4.5	<u>Form of Common Stock Purchase Warrant issued by Ensysce Biosciences, Inc. pursuant to and in accordance with a 2022 Securities Purchase Agreement (incorporated by reference to Exhibit 4.7 filed with the registrant's Current Report on Form 8-K (File No. 001-38306) on August 9, 2022).</u>
4.6	<u>Form of warrant delivered by Ensysce Biosciences, Inc. in December 2022 in connection with an underwritten offering (incorporated by reference to Exhibit 4.10 filed with the registrant's Post-Effective Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-268038) filed December 8, 2022).</u>
4.7	<u>Form of pre-funded warrant delivered by Ensysce Biosciences, Inc. in December 2022 in connection with an underwritten offering (incorporated by reference to Exhibit 4.11 filed with the registrant's Post-Effective Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-268038) filed December 8, 2022).</u>
4.8	<u>Form of warrant issued in connection with a private placement conducted concurrently with a public offering (incorporated by reference to Exhibit 4.1 filed with the registrant's Current Report on Form 8-K (File No. 001-38306) on February 7, 2023).</u>
4.9	<u>Form of warrant issued to a placement agent or its designees in connection with a private placement conducted concurrently with a public offering (incorporated by reference to Exhibit 4.2 filed with the registrant's Current Report on Form 8-K (File No. 001-38306) on February 7, 2023).</u>
4.10	<u>Form of common warrant (incorporated by reference to Exhibit 4.12 filed with the registrant's Post-Effective Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-271480) on May 17, 2023).</u>
4.11	<u>Form of pre-funded warrant (incorporated by reference to Exhibit 4.13 filed with the registrant's Post-Effective Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-271480) on May 17, 2023).</u>
4.12	<u>Form of placement agent warrant (incorporated by reference to Exhibit 4.14 filed with the registrant's Post-Effective Amendment on Form S-1 (File No. 333-271480) on May 17, 2023).</u>
4.13	<u>Form of warrants amended in connection with the execution of a Securities Purchase Agreement on May 10, 2023 (incorporated by reference to Exhibit 4.15 filed with the registrant's Post-Effective Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-271480) on May 17, 2023).</u>
4.14	<u>Form of common warrant issued in October 2023 and November 2023 (incorporated by reference to Exhibit 4.16 filed with the registrant's Registration Statement on Form S-1 (File No. 333-275456) on November 9, 2023).</u>
4.15	<u>Form of October 2023 Secured Convertible Promissory Note (incorporated by reference to Exhibit 4.6 filed with the registrant's Current Report on Form 8-K (File No. 001-38306) on October 24, 2023).</u>
4.16	<u>Form of Series A/B common stock purchase warrant issued February 14, 2024 (incorporated by reference to Exhibit 4.1 filed with the registrant's Current Report on Form 8-K (File No. 001-38306) on February 14, 2024).</u>
4.17	<u>Form of placement agent warrant issued February 14, 2024 (incorporated by reference to Exhibit 4.2 filed with the registrant's Current Report on Form 8-K (File No. 001-38306) on February 14, 2024).</u>
4.18	<u>Form of Series A-3/A-4 common stock purchase warrant issued August 29, 2024 (incorporated by reference to Exhibit 4.2 filed with the registrant's Current Report on Form 8-K (File No. 001-38306) on August 30, 2024).</u>
4.19	<u>Form of Series A-5/A-6 common stock purchase warrant issued March 31, 2025 (incorporated by reference to Exhibit 4.2 filed with the registrant's Current Report on Form 8-K (File No. 001-38306) on March 31, 2025).</u>
4.20	<u>Form of placement agent warrant issued March 31, 2025 (incorporated by reference to Exhibit 4.3 filed with the registrant's Current Report on Form 8-K (File No. 001-38306) on March 31, 2025).</u>

5*	<u>Opinion of Troutman Pepper Locke LLP.</u>
23.1*	<u>Consent of Troutman Pepper Locke LLP (included in Exhibit 5).</u>
23.2*	<u>Consent of Moss Adams LLP.</u>
24.1*	<u>Power of Attorney (included on signature page to this registration statement).</u>
107*	<u>Filing Fee Table.</u>

* Filed herewith.

** To be filed by amendment.

*** Previously filed.

† Certain schedules (or similar attachments) to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5) or 601(b)(2), as applicable. The registrant agrees to furnish supplementally a copy of all omitted schedules to the Securities and Exchange Commission upon its request.

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Item 17. Undertakings.

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement: (i) to include any prospectus required by Section 10(a)(3) of the Securities Act; (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement (notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Filing Fee Tables" or "Calculation of Registration Fee" table, as applicable, table in the effective registration statement); and (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser: (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§ 230.424 of this chapter); (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant; (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (5) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (6) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in City of San Diego, State of California, on April 16, 2025.

ENSYSCE BIOSCIENCES, INC.

By: /s/ Dr. Lynn Kirkpatrick

Name: Dr. Lynn Kirkpatrick

Title: President, Chief Executive Officer and Director

Each person whose signature appears below constitutes and appoints each of Dr. Lynn Kirkpatrick and David Humphrey, acting alone or together with another attorney-in-fact, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for such person and in his or her name, place and stead, in any and all capacities, to sign any or all further amendments (including post-effective amendments) to this registration statement (and any additional registration statement related hereto permitted by Rule 462(b) promulgated under the Securities Act of 1933 (and all further amendments, including post-effective amendments, thereto)), and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities indicated on April 16, 2025.

Name	Title
By: <u>/s/ Dr. Lynn Kirkpatrick</u>	President, Chief Executive Officer and Director

Dr. Lynn Kirkpatrick	(Principal Executive Officer)
By: <u>/s/ David Humphrey</u> David Humphrey	Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)
By: <u>/s/ Andrew Benton</u> Andrew Benton	Director
By: <u>/s/ William Chang</u> William Chang	Director
By: <u>/s/ Bob Gower</u> Bob Gower	Director and Chairman of the Board
By: <u>/s/ Adam Levin</u> Adam Levin	Director
By: <u>/s/ Steve Martin</u> Steve Martin	Director
By: <u>/s/ Lee Rauch</u> Lee Rauch	Director
By: <u>/s/ Curtis Rosebraugh</u> Curtis Rosebraugh	Director

Troutman Pepper Locke LLP
 Union Trust Building, 501 Grant Street, Suite 300
 Pittsburgh, PA 15219-4429



troutman.com

April 16, 2025

Ensysce Biosciences, Inc.
 7946 Ivanhoe Avenue, Suite 201
 La Jolla, California 92037

Re: Securities Registered under Registration Statement on Form S-3

Ladies and Gentlemen:

We have acted as counsel to Ensysce Biosciences, Inc., a Delaware corporation (the “Company”), in connection with the registration statement on Form S-3 (the “Registration Statement”) filed with the Securities and Exchange Commission (the “SEC”), and a related prospectus included in the Registration Statement (the “Prospectus”), on April 16, 2025. The Registration Statement relates to the registration under the Securities Act of 1933, as amended (the “Act”), by the Company of an aggregate of 652,439 shares (the “Shares”) of the Company’s common stock, par value \$0.0001 per share (the “Common Stock”), consisting of (i) 315,188 shares of Common Stock (the “Series A-5 Warrant Shares”) issuable upon exercise by the selling stockholders named in the Prospectus (the “Selling Stockholders”) of Series A-5 warrants (the “Series A-5 Warrants”), (ii) 315,188 shares of Common Stock (the “Series A-6 Warrant Shares”) issuable upon exercise by the Selling Stockholders of Series A-6 warrants (the “Series A-6 Warrants”), and (iii) 22,063 shares of Common Stock (the “Placement Agent Shares”) and together with the Series A-5 Warrant Shares and Series A-6 Warrant Shares, the “Warrant Shares”) that are issuable to certain Selling Stockholders upon the exercise of certain Placement Agent Warrants (the “Placement Agent Warrants,” and together with the Series A-5 Warrants and the Series A-6 Warrants, the “Warrants”). The Series A-5 Warrants and Series A-6 Warrants were issued by the Company pursuant to a securities purchase agreement (the “SPA”) entered into by and among the Company and the Selling Stockholders on March 30, 2025. The Placement Agent Warrants were issued by the Company in connection with the SPA pursuant to an engagement letter agreement, as amended (as amended, the “Engagement Agreement”), entered into between the Company and H.C. Wainwright & Co., LLC.

This opinion is being furnished in accordance with the requirements of Item 16(a) of Form S-3 and Item 601(a) and (b)(5)(i) of Regulation S-K.

For purposes of the opinions we express below, we have examined the originals or copies, certified or otherwise identified, of (i) the Registration Statement, (ii) the Company’s Third Amended and Restated Certificate of Incorporation and the Amended and Restated Bylaws of the Company, each as amended and/or restated to date, (iii) the SPA, (iv) the Engagement Agreement and (v) such other instruments and documents as we considered appropriate for purposes of the opinions hereafter expressed.

In connection with rendering the opinions set forth below, we have assumed without verification (i) the authenticity of all documents submitted to us as originals, (ii) the conformity to the originals of all documents submitted as certified, photostatic or electronic copies and the authenticity of the originals thereof, (iii) the legal capacity of natural persons, (iv) the genuineness of signatures not witnessed by us, including electronic signatures, (v) the due authorization, execution and delivery of all documents by all parties, other than the Company, and the validity, binding effect and enforceability thereof, and (vi) the truth, accuracy and completeness of the information, representations and warranties contained in the records, documents, instruments and certificates we have reviewed.

With respect to the Warrant Shares, we express no opinion to the extent that, notwithstanding the Company’s current reservation of shares of Common Stock, future issuances of securities of the Company and/or anti-dilution adjustments to outstanding securities of the Company may cause the exercise of the Warrants for more shares of Common Stock than the number that then remain authorized but unissued. Further, we have assumed the exercise prices of the Warrants will not be adjusted to an amount below the par value per share of the shares of Common Stock.

Troutman Pepper Locke LLP
 Union Trust Building, 501 Grant Street, Suite 300
 Pittsburgh, PA 15219-4429



troutman.com

As to factual matters, we have relied upon the documents furnished to us by the Company, the certificates and other comparable documents of officers and representatives of the Company, statements made to us in discussions with the Company’s management and certificates of public officials, without independent verification of their accuracy.

We are opining as to the General Corporation Law of the State of Delaware, and we express no opinion with respect to any other laws. We are not opining as to the applicability thereto, or the effect thereon, of the laws of any other jurisdiction or, in the case of Delaware, any other laws, or as to matters of municipal law or the laws of any local agencies within any states (including “blue sky” or other state securities laws).

Regarding our opinion concerning the Warrants constituting valid and binding obligations of the Company:

(i) Our opinion is subject to, and may be limited by, (a) applicable bankruptcy, reorganization, insolvency, moratorium, fraudulent conveyance, debtor and creditor, and similar laws which relate to or affect creditors’ rights generally, and (b) general principles of equity (including, without limitation, concepts of materiality, reasonableness, good faith and fair dealing) regardless of whether considered in a proceeding in equity or at law.

(ii) Our opinion is subject to the qualification that the availability of specific performance, an injunction or other equitable remedies is subject to the discretion of the court before which the request is brought.

(iii) We express no opinion as to any provision of the Warrants that: (a) provides for liquidated damages, buy-in damages, monetary penalties, prepayment or make-whole payments or other economic remedies to the extent such provisions may constitute unlawful penalties, (b) relates to advance waivers of claims, defenses, rights granted by law, or notice, opportunity for hearing, evidentiary requirements, statutes of limitations, trial by jury, or procedural rights, (c) restricts non-written modifications and waivers, (d) provides for the payment of legal and other professional fees where such payment is contrary to law or public policy, (e) relates to exclusivity, election or accumulation of rights or remedies, (f) authorizes or validates conclusive or discretionary determinations, or (g) provides that provisions of the SPA, the Engagement Agreement and the Warrants are severable to the extent an essential part of the agreed exchange is determined to be invalid and unenforceable.

(iv) We express no opinion as to whether a state court outside of the State of New York or a federal court of the United States would give effect to the choice of New York law provided for in the SPA, the Engagement Agreement and the Warrants. We also express no opinion as to compliance with any federal securities laws.

Based on the foregoing and in reliance thereon, and subject to the limitations, qualifications, assumptions, exceptions and other matters set forth herein, we are of the opinion that:

(1) The Warrants are legal, valid and binding obligations of the Company, enforceable against the Company in accordance with their terms.

(2) The Warrant Shares, when issued by the Company against payment therefore in accordance with the terms of the Warrants, the SPA and the Engagement Agreement, as applicable, will be validly issued, fully paid and non-assessable.

Our opinion is as of the date hereof and we have no responsibility to update this opinion for events and circumstances occurring after the date hereof or as to facts relating to prior events that are subsequently brought to our attention and we disavow any undertaking to advise you of any changes in law.

We hereby consent to the filing of this opinion letter as Exhibit 5 to the Registration Statement and to the use of our name under the caption "Legal Matters" in the Registration Statement and in the Prospectus forming a part thereof and any supplement thereto. In giving this consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the SEC promulgated thereunder.

Very truly yours,

/s/ Troutman Pepper Locke LLP

TROUTMAN PEPPER LOCKE LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement on Form S-3 of Ensysce Biosciences, Inc. (the “Company”) of our report dated March 10, 2025, related to the consolidated financial statements of the Company (which report expresses an unqualified opinion and includes an explanatory paragraph regarding the existence of substantial doubt about the Company’s ability to continue as a going concern). We also consent to the reference to us under the heading “Experts” in such Registration Statement.

/s/ Moss Adams LLP

San Diego, California
April 16, 2025

Calculation of Filing Fee Tables

Form S-3
(Form Type)Ensysce Biosciences, Inc.
(Exact Name of Each Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered ⁽¹⁾	Proposed Maximum Offering Price Per Unit ⁽²⁾	Maximum Aggregate Offering Price ⁽²⁾	Fee Rate ⁽²⁾	Amount of Registration Fee ⁽²⁾	Carry Forward Form Type	Carry Forward File Number	Carry Forward Initial effective date	Filing Fee Previously Paid In Connection with Unsold Securities to be Carried Forward
Newly Registered Securities											
	Common Stock, par value \$0.0001 per share (“Common Stock”) underlying warrants to purchase Common										
Fees to Be Paid	Equity	Stock ⁽³⁾	457(c)	652,439(3)	\$ 1.87	\$ 1,220,061	\$ 186.79				
Fees Previously Paid							\$ -				
Carry Forward Securities											
Carry Forward Securities											
	Total Offering Amounts					\$ 1,220,061	\$ 186.79				
	Total Fees Previously Paid						-				
	Total Fee Offsets						-				
	Net Fee Due						\$ 186.79				

- (1) The shares of the Registrant’s common stock, par value \$0.0001 per share (the “Common Stock”), offered hereby also include such presently indeterminate number of shares of Common Stock as a result of stock splits, stock dividends or similar transactions in accordance with Rule 416 under the Securities Act of 1933, as amended (the “Securities Act”).
- (2) Pursuant to Rule 457(c) under the Securities Act, and solely for the purpose of calculating the registration fee at a fee rate of 0.0001531 (\$153.10 per \$1 million), the proposed maximum offering price per share is \$1.87, which is the average of the high and low prices of the Common Stock as reported on The Nasdaq Capital Market on April 10, 2025, which date is within five business days prior to filing this Registration Statement.
- (3) Represents an aggregate of 652,439 shares of common stock registered for sale by the selling stockholders named in this registration statement consisting of: 315,188 shares of Common Stock, underlying those certain Series A-5 warrants, 315,188 shares of Common Stock underlying those certain Series A-6 warrants, and 22,063 shares of Common Stock underlying those certain Placement Agent Warrants that were issued in certain private transactions described herein (after giving effect to certain potential anti-dilution and other adjustments).